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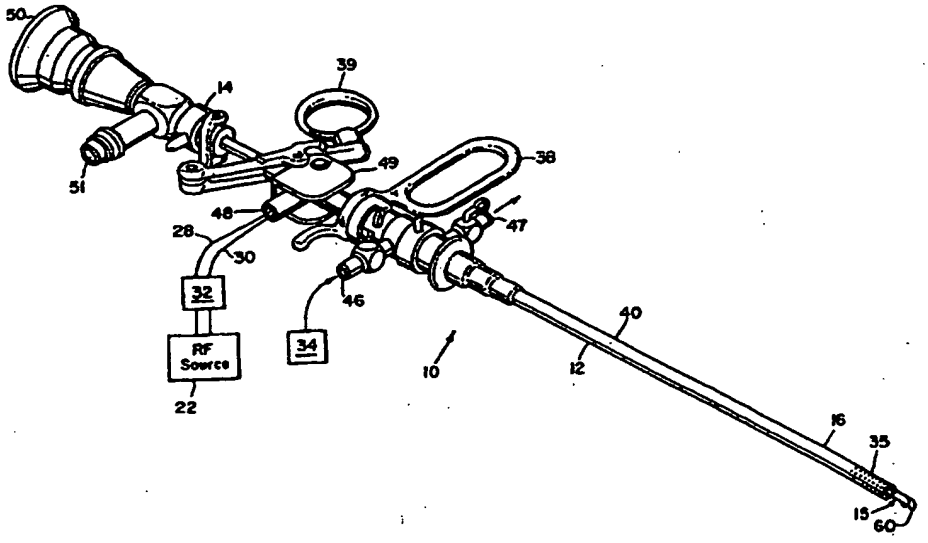

(57) Abstract

The hysteroscopic electrosurgical device (10) includes a probe (12) having a proximal end (14) and a distal end (16) and having a first conductive element (25) that conducts an electrical signal from the proximal end (14) to the distal end (16) and a second conductive element (27) extending from the distal end (16) to the proximal end (14). An electrode assembly (15) is at the distal end (16) of the probe (12) to remove tissue at a surgical site within a body lumen. A first fluid channel (29) within the probe (12) supplies a flow of isotonic fluid through an aperture (33) at the distal end (16) of the probe (12) into a body lumen. A second fluid channel (31) is within the probe (12) allows fluid adjacent to the distal end (16) to be removed to the proximal end (14). A generator (22) is connected to the proximal end of the probe (12) to provide an electrical signal to the electrode assembly (15) in order to cut and cauterize tissue at the surgical site. The device (10) can be used during intrauterine endoscopic surgery in combination with an isotonic solution.

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APPARATUS AND METHOD FOR ELECTROSURGERY

Related Applications

This is a Continuation-in-Part application of U.S. Serial No. 08/628,941, filed on April 8, 1996 which is a continuation-in-part application of U.S. Serial No. 08/581,244 filed on December 29, 1995, the entire contents thereof being incorporated herein by reference.

Background of the Invention

Therapeutic hysteroscopy is a series of procedures in which a surgeon performs an operative technique within the uterine cavity of a woman utilizing a hysteroscope which is placed through the cervix. The procedures are considered minimally invasive surgery because they do not require any incision and are usually performed on an outpatient basis. Examples of procedures with the hysteroscope include the removal of submucous fibroids, polypectomies, removal of intrauterine adhesions, correction of congenital uterine defects and endometrial ablation, a procedure performed to correct abnormal uterine bleeding.

Operative hysteroscopy utilizes high frequency electrical energy for cutting and coagulation. At present, a monopolar system is utilized which includes high frequency electrical energy that is directed from a generator through a hysteroscopic wire loop or ball and passes through the patient and returns to the generator by way of a return electrode usually placed on the patient's thigh.

The uterine cavity is a potential space and therefore, during a hysteroscopy, the uterine cavity must be distended in order for the surgeon to see. Typically, the pressure

necessary to distend the uterine cavity is in the range of between about 60 and 80 mm Hg. This pressure is higher than venous pressure, approximately 20 mm Hg, and is close to the range of the mean arterial pressure. In order to use a monopolar system inside the uterus, a medium, which is necessary to distend the cavity must be electrolyte-free (hypotonic) or the current dissipates and is ineffective. Therefore, if a uterine vessel is cut during surgical hysteroscopy, the distending fluid can enter a patient's blood stream. If too much hypotonic solution enters the bloodstream, dangerous electrolytic disturbances can occur, which can lead to cardiac arrhythmia, brain swelling and sudden death.

Therefore, a need exists for an instrument and a method for using the instrument that overcomes the problems described above.

Summary of the Invention

The present invention relates to an intralumen or intracavity electrosurgical device and a method for using the instrument, and particularly to the use of the device for surgical procedures within the uterine cavity.

The hysteroscopic electrosurgical device includes a probe having a proximal end and a distal end and having a first conductive element or delivery electrode that conducts an electrical signal from the proximal end to the distal end and a second conductive element or return electrode extending from the distal end to the proximal end. An electrode assembly is at the distal end of the probe. A fluid channel within the probe supplies a flow of a fluid, preferably an isotonic solution, through an aperture at the distal end of the probe into a body cavity or lumen. A fluid collection lumen collects fluid exiting the probe. A generator is connected to the proximal end of the probe to provide an electrical signal to the first

conductive element and the second conductive element at the proximal end of the probe.

The method includes inserting an isotonic fluid into the uterus of the patient. The type of fluid used is specifically selected to reduce or eliminate the adverse effects associated with using solutions having electrolyte concentrations that can alter electrolyte levels in the bloodstream. This substantially reduces the risk to the patient and provides increased flexibility to the surgeon. For certain patients, where electrolyte imbalance is critical, the concentrations of certain blood analytes can be measured before and/or during surgery. The concentration level of certain analytes can then be adjusted in the fluid being inserted into the uterus or through the urethra to minimize the risk of electrolyte imbalance.

After insertion of the hysteroscope into the uterus, the electrode system at the distal end of the device is positioned relative to a surgical site in the uterus. An electrical signal is applied to the electrode and thereby removes tissue at the surgical site while providing a flow of isotonic fluid to a region proximate to the electrode. The tissue is cut or heated with the electrode. The system is used specifically to treat dysfunctional uterine bleeding, benign fibroid tumors or polyps, or those needing endometrial ablation or resection. In an alternative embodiment, the device is used for urological applications including transurethral resection of the prostate.

The operational frequency range of the device is between 100KHz and 2MHz, and preferably in the range of 500KHz to 0.5 MHz. It is generally desirable to initiate cutting at lower power levels and increase as necessary to optimize the speed and efficiency of the procedure. For certain electrode configurations it may be necessary to initiate cutting temporarily at higher power and then

reduce power, particularly with return electrodes with relatively small surface areas.

A preferred embodiment of the electrode assembly is a bipolar electrode system having first and second loops. Current is conducted between the gap separating the two loops by the fluid at the surgical site. The fluid is preferably transparent to optimize the surgeon's view of the operative site and is continuously flowing to remove debris. For the purposes of the present application a bipolar system includes at least two conductive pathways extending through the probe, one delivering current to a treatment electrode and the second acting as a return path. As described below, there are bipolar systems for the present invention having more than two electrodes.

In another preferred embodiment a sheath or cannula of the probe can serve as the return electrode of the bipolar system. The sheath can be a disposable sheath made with a rigid dielectric material that can be mounted directly to existing monopolar devices with a coupling mechanism such as a luer fitting to provide a bipolar system. The electrode can be formed on the distal end of the sheath with an insulated wire connecting the electrode along a wall of the sheath to a connector on the proximal end of the sheath. Alternatively, in another embodiment, the inner or outer sheaths or cannulas used to control fluid flow can be formed with a conductive metal such as stainless steel, and with proper connection at the proximal end, these can be used as return electrodes.

Another preferred embodiment of the electrode assembly provides a third electrode at the distal end of the probe that is used to determine whether the cutting electrode and the return electrode are both immersed in solution. Only when the pair of return electrodes are both immersed in solution will current be delivered to the electrode assembly for treatment. This system provides a safety

circuit to prevent unwanted damage to tissue when there is not a proper return path through the electrode assembly.

Brief Description of the Drawings

Figure 1A shows a perspective view of an electrosurgical device of the present invention.

Figure 1B shows a perspective view of the electrodes of the device shown in Figure 1.

Figure 1C shows a cut-away cross sectional view of the probe of the device shown in Figure 1.

Figure 2 shows a schematic perspective view of the electrodes having two loops.

Figure 3 shows a schematic perspective view of the electrodes having a roller system.

Figure 4 shows a schematic block diagram of an electrosurgical system in accordance with the invention system useful for controlling the temperature of electrodes.

Figure 5 shows a block diagram illustrating a method of using the device.

Figure 6 illustrates another embodiment of a bipolar electrode assembly in accordance with the invention. Figure 7A and 7B illustrate side and cross-sectional views of a bipolar electrosurgical system in accordance with the invention.

Figure 8 is a detailed cross-sectional view of a luer fitting for coupling a disposable sheath to an electrosurgical system in accordance with the invention.

Figure 9 is a partial cross-sectional view of a disposable sheath using an insulated cannula as the return electrode.

Figure 10 is a partial schematic circuit diagram illustrating a safety system having three electrodes.

Figure 11 is another preferred embodiment of the invention.

Figure 12 is a detailed view of a hub assembly in accordance with the invention.

Figure 13A and 13B are detailed views of the distal end of a probe assembly.

Figures 14A-14D illustrate a preferred embodiment of a hub connector in accordance with the invention.

Figures 15A and 15B illustrate prior art devices with the outer tubes partially separated.

Figures 16A and 16B illustrate additional preferred embodiments of sheath assemblies in accordance with the invention.

Detailed Description of the Invention

Features and other details of the method and apparatus of the invention will now be particularly described with reference to the accompanying drawings and pointed out in the claims. The same numerals present in different figures represents the same item. It will be understood that the particular embodiments of the invention are shown by way of illustration and not as limitations of the invention. The particular features of this invention can be employed in various embodiments without departing from the scope of the invention. All parts and percentages are by weight unless otherwise specified.

Figure 1A illustrates the hysteroscopic, electrosurgical device 10 of the present invention. The device 10 includes probe 12 having proximal end 14 and distal end 16. Probe 12, as shown in the cut-away view in Figure 1C, includes an outer wall 17, an inner wall 19, an optical path 21, and conductive assembly 23 that includes a first conductive element 25 that conducts an electrical signal from the proximal end 14 to the distal end 16 and a second conductive element 27 extending from the distal end 16 to the proximal end 14. Although schematically shown as separate first conductive element 25 and second conductive

element 27, the elements are often encased in an insulated rod for protection and support. A first fluid channel 29 is formed within inner sheath 19 for allowing isotonic fluid to flow to an aperture at the distal end of the probe 12. Optical path 21 and conductive assembly are within first fluid channel 29. Second fluid channel 31 is formed between outer sheath 17 and inner sheath 19. Second fluid channel 31 allows fluid proximate to the distal end 16 to proximal end 14.

Turning to Figure 1B, distal end 16 comprises an aperture 33 from which electrode assembly 15 with retractable electrodes 18,20 can project from the distal end 16 of probe 12. First fluid channel 29 ends at aperture 33 through which fluid can exit probe 12. Distal end 16 has fluid inlet 35, which can be a series of apertures, for removing fluid proximate to the exterior of probe. Fluid is removed from fluid inlet 35 through second fluid channel 31 to fluid outlet port 47. Distal end 16 can have beak 37 extending from inner wall 19 defining the aperture 33. Beak 37 can be formed of a ceramic, such as porcelain, to act as a shield and protective insulator to prevent arcing during the procedure.

Electrodes 18,20 can have two loops, including first and second electrodes for providing bipolar cauterization or cutting. Electrical leads 28,30 are connected at one end to power source 22 through electrical connectors 24,26 and at the other end through an actuator to conductive assembly 23 to electrodes 18,20, respectively. Power supply 22 can be activated to supply an alternating current voltage to electrodes 18,20. An example of a suitable bipolar RF generator is disclosed in U.S. 5,318,563, issued to Malis *et al.* on June 7, 1994, the teachings of which are herein incorporated by reference.

The bipolar conduction process results in the localized heating of tissue and tissue regions adjacent the

electrodes. This localized heating results in elevated temperatures sufficient to cause selective necrosis and hemostasis of the tissue or tissue separation for cutting. The bipolar feature of the instrument provides that the conduction of current through tissue or fluids remote from the operative tissue is minimal.

The device 10 includes a radio frequency energy source 22, a control unit 32, in electrical communication with the energy source 22, and an electrosurgical probe 12. The control unit 32 is in electrical communication with probe 12 through electrode leads 28,30.

A fluid source or reservoir 34 provides a fluid to probe 12 through conduit 46. In contrast to other intrauterine procedures the present invention utilizes an isotonic fluid, such as saline or Ringer's lactate. An isotonic solution is one having the same osmotic pressure as another solution, such as human blood and a physiological salt solution. For use with this invention, an isotonic solution includes solutions which, when in cells of the patient, neither swell nor shrink, thereby minimizing any dangerous electrolytic disturbances to the body. For humans, an isotonic solution has an osmolarity in the range of between about 260 and 295 milliosmols per liter. In a preferred embodiment, the osmolarity of the isotonic fluid is in the range of between about 280 and 290 milliosmols per liter. A hypotonic solution is considered one with less than about 260 milliosmols per liter, and a hypertonic solution is considered one with greater than about 295 milliosmols per liter.

Probe 12 has a handle portion 38 at its proximal end 14 and an elongate member 40 that extends from the handle portion 38. The distal end 16 of elongate member 40 includes electrode elements 18,20. Electrode elements 18,20 are able to extend from, or to be retracted within, a

substantially circular orifice, which preferably is disposed in the distal end of the probe.

The handle portion 38 of probe 10 includes a fluid inlet port 46 that communicates with fluid source 34 through conduit and allows fluid directed through first fluid channel 29 to distal end 16. Fluid removed by probe through second fluid channel 31 exits fluid outlet port 47. Electrode leads 28,30 emerge from cuff 48 on working element 49 on the handle portion 38 of the probe 12. The proximal ends of electrode leads 28,30 are connected to control unit 32. The distal ends of leads 28,30 connect through conductive assembly 23 to electrode elements 18,20, respectively. The electrode elements 18,20 are connected to an extender, such as an Iglesis extender which pushes the electrodes in and out of the probe 12.

A video camera can be connected to eyepiece 50 on resectoscope to allow viewing of electrode elements 18,20 during cutting. The video camera can be connected to a television monitor. Within elongated member 40, of probe 12 is optical path 21, such as a solid glass lens, a plurality of lens fitted within a tubular metal housing or fiber optic cable. Light for viewing the procedure is directed through light delivery port 51 to optical path 21 from a light source, such as a xenon lamp, not shown.

Electrode elements 18,20 preferably are coated with an insulating material 54 over its entire length, except for its extreme distal end which is uncoated so as to deliver electrosurgical energy to tissue. Suitable insulating materials include polymers such as polyvinylidene chloride, polytetrafluoroethylene, fluorinated ethylene-propylene polymers, polyethylene, and others known to be suitable for use in medical applications.

Referring to Figure 1C, first fluid channel 29 preferably is centrally located within probe 12 and extends throughout the length of the handle portion 38 and elongate

member 40, along the longitudinal axis of the probe 12. A fluid from source 34 is able to be communicated to inlet port 46 to allow fluid to be delivered through first fluid channel 29 to aperture 33 where it is discharged from the probe to contact tissue. Viewing lens 58 is located at aperture 33 to allow viewing of electrodes 60,62.

As noted, conductive elements 25,27 are positioned within and extend over the entire length of elongate member 40. The selectively deployable nature of electrode elements 18,20 has the advantageous deploying the treatment electrode 60 for a cutting and/or cauterization procedure and retracted during insertion and withdrawal of probe 12.

Deployment of electrode elements 18,20 can be controlled by a suitable mechanism preferably mounted on the handle portion 38 and trigger 39 of probe 12. A thumb actuated mechanism can be mounted upon the proximal end of device and can be used to control the retraction and extension of the electrode elements 18,20. In another embodiment, an excess length of conductive elements 25,27 can extend from the proximal end 14 of handle 38 to allow manual manipulation to regulate the length of electrodes 60,62 extending from orifice. A variety of other length controlling mechanisms can be utilized as well, as are known in the art.

Dimensions of the probe 12 are such that it is suitable for use in arthroscopic, endoscopic, hysteroscopic, urologic, resectoscopic, laproscopic and general surgery. Preferably, the length of the probe 12 is in a range of between about 25 and 45 cm. The diameter of the member can vary within a range of dimension known in the art to be suitable for the extended use of the probe. The probe 12 of the present invention can be manufactured of a variety of materials including metals, polyolefins and nylons that are known to be suitable for use in medical applications. The outer wall 17 and inner wall 19 of probe

preferably are manufactured of stainless steel. The electrode elements 18,20 are preferably made from a highly conductive material such as gold, silver, or platinum, or other materials such as tungsten or stainless steel. The conductive material from which the electrodes are made can be a solid material, or alternatively, a plating which is deposited upon an insulating material, such as a polymer or ceramic. The electrode elements 18,20 should have sufficient rigidity, tensile strength and compressive strength to enable it to be extended from and retracted within the probe 12.

The diameter of cutting surface can also vary, and its size depends to a large extend upon the diameter of first fluid channel 29. One requirement of the first fluid channel diameter is that it be sufficient to accommodate the flow of fluid while electrode elements 18,20 are disposed within the first fluid channel 29. Generally, the first fluid channel diameter is in the range of about 1 to 5 mm, while the width of electrode elements 18,20 range from about 1 to 5 mm, with a preferred range of about 3 mm.

In an operation, the probe 12 can be inserted through the cervix or an incision and directed to the location at which the surgical procedure is to be performed. Cutting electrode elements 18,20 can be extended from within the first fluid channel 29 once the probe 12 reaches the surgical site. Thereafter, electrosurgical energy can be delivered through electrode elements 18,20 to either cutting surface 60,62.

In an alternative embodiment, one loop can be removed and the sheath 17 can include a return electrode 55 on the outer surface. The electrode is connected to the generator with an insulated wire 57 that extends along the length of the sheath to a connector. The electrode 55 can also serve as a third electrode in a three electrode system as described in greater detail below.

Figure 2 shows an embodiment of the front portion of the electrosurgical device 10 without the endoscope displayed. Two insulated cables with electrode elements 18,20 and insulation 54 are connected from the electrical power source 22 through the endoscope. At the distal end are arranged a first cutting loop 60 and a second cutting loop 62. The first cutting loop 60 is electrically conductively connected at one end with electrode element 18 and at other with electrode element 20. The second cutting loop 62, which is parallel to first cutting loop 60, and closer to the proximal end 14 of the probe 12, is similarly electrically conductively connected to provide a cutting electrode or a return electrode. Second cutting loop 62 can have the same size radius as first cutting loop 60. Alternatively, second cutting loop 62 can have a smaller size arc radius than first cutting loop 60. The second loop can be connected to a second set of electrodes separately from electrode elements 18,20 and controlled separately be a second control unit. First cutting loop 60 and second cutting loop 62 are sized to allow the loops to be retracted fully into the first fluid channel 29.

Figure 3 shows another embodiment of the front portion of the electrosurgical device without the endoscope displayed. Two insulated cables with electrode elements 18,20 and insulation 54 are connected from the electrical generator 22 through the endoscope. At the front end are arranged a first roller 64 connected to electrode element 18 and a second roller 66 connected to second electrode element 20 on the same axis about which the two rollers can rotate. The rollers can each have a diameter in the range of between about 1 and 5 mm and a width in the range of between about 1 and 4 mm. First roller 64 and second roller 66 are spaced in the range of between about 0.5 and 2 mm. In a preferred embodiment, first roller 64 and second roller 66 are spaced about 1 mm apart.

Alternatively, an insulative material can be inserted between first roller 64 and second roller 66. In one embodiment, the insulative material includes polyethylene and has a thickness in the range of between 0.5 and 2 mm. First roller 64 and second roller 66 can independently rotate about their axis. Further, each roller is respectively connected to electrode elements 18,20 for electrical contact.

During cutting procedures, fluid is delivered through first fluid channel 29 at a desired rate. Delivery of fluids acts to limit the heat transfer from the cauterization to adjacent tissue to an extent that the tissue does not become overly heated by electrodes causing tissue and coagulation to stick to tip. The fluid also serves as an irrigant to improve the visibility in the area subject to surgery and to remove any debris from the surgical site while maintaining an essentially isotonic environment for any possible leakage of fluid into the bloodstream. One of ordinary skill in the art will appreciate that the fluid flow rate depends on a number of variables, including the temperature of the fluid and the amount of power delivered to the cauterization electrode and the mean arterial pressure of the patient. The fluid flow rate may be constant or variable. The flow is preferably continued as long as the probe 12 is within the uterus.

The fluid flow rate can depend upon a number of variables including the inflow pressure, the tubing diameter, the outflow diameter, the mean arterial pressure of the patient, and the amount of bleeding or degradation. Pressure transducers to monitor the pressure of the fluid are attached at the inlet port 46 and outlet port 47. The pressure within the uterine cavity can be calculated based on the differential between the two transducers.

Alternatively, pressure transducer can be directly placed in the uterus with the device.

The flow rate can be adjusted to accommodate the requirements of a variety of surgical procedures. The fluid source is connected with a valve or pump mechanism which controls the flow rate of the fluid through first fluid channel 29. The flow rate can be constant at a predetermine rate, such as about 50 milliliters per minute, which generally is sufficient to maintain visibility at the surgical site.

An irrigation fluid collection chamber and associated effluent channel for exhausting irrigation fluid of the uterine probe of the present invention is connected with the external diameter of the interuterine sheath for receipt of irrigation fluid emanating from the uterus. Such effluent fluid may be in the form of irrigation liquid which is injected within the uterus by ports disposed at the distal portion of the medical instrument to provide a constantly flowing irrigation field within the uterus, *inter alia*, for the purpose of flushing away any debris removed from the uterus by the surgical instrument, and also to provide a clear and transparent operative field for the light emitting photoscopic mechanism disposed at the distal end of the medical instrument, such as a hystoscope. In addition, by monitoring the volume and flow rate of the fluid discharged from the uterus and comparing such discharge volume with the monitored volume and flow rate of the isotonic fluid charged to the uterus, the possibility of a uterine perforation can be detected by these means.

Figure 4 shows a block diagram that is representative of the system used to conduct electrosurgery with the probe 80. An RF signal is delivered to electrode from generator unit 82 and applied to tissue 84. A camera 85 can be connected to the optical system within the probe to provide

an image of the surgical site for display 87 by the user during the procedure and to record the procedure.

During cutting, fluid is delivered through first fluid channel 29 at a desired rate. The delivery of fluid serves at least four purposes. First, the fluid acts to limit the heat transfer from electrode elements 18,20 to adjacent tissue to an extent that tissue does not become overly heated by the electrodes, causing tissue and/or coagulant to stick to the electrodes. This allows more effective and convenient cutting. Second, fluid delivered to tissue can also serve as an irrigant to improve the visibility in the area subject to surgery and to remove any debris from the surgical site. A mechanical grinding unit can be integrated into the device at the tip or elsewhere to grind the removed debris. Third, the fluid is used to distend the uterine cavity and as a conductor between the treatment electrode and the return electrode. Fourth, the isotonic fluid allows a bipolar instrument to be used, while reducing the danger of a hypotonic solution from entering the bloodstream.

One of ordinary skill in the art can appreciate that the fluid flow rate depends on a number of variables, including the temperature of the fluid and the amount of power delivered to the electrodes. The fluid flow rate may be constant or variable. Preferably, the flow rate is variable and occurs only when energy is delivered to effect cauterization and cutting and preferably ranges from approximately 25 to 75 ml/minute.

The flow rate should be effective to control the temperature of the electrodes, but the temperature should not be so high as to vaporize tissue unless cutting tissue is desired. The electrode temperature should be maintained below about 60°C, and more preferably below about 46°C. The temperature of the fluid may range from quite cold

(e.g., about 4°C) to about room temperature or higher (e.g., about, 27°C).

Flow rate can be manually adjusted or can be controlled by one or more feedback mechanisms that monitor impedance.

One skilled in the art can readily appreciate that certain surgical procedures will be able to tolerate more fluid flow while others will be able to tolerate less. The fluid flow rate can be adjusted to accommodate the requirements of a variety of surgical procedures.

The fluid source 34 may communicate with a valve or pump mechanism (not shown) which controls the flow rate of fluid through first fluid channel 29. The flow rate can be constant at a predetermined rate, such as about 30 ml/minute. A micropump can be attached to the device to provide additional pressure to the cavity as needed during the surgical procedure.

The delivery of energy through electrode elements 18,20 to cauterize tissue causes the temperature of the electrodes to rise significantly. Excess heating of the electrodes (e.g., above about 60°C) can damage tissue and result in the buildup of excess coagulant on the cauterization electrode of probe 12. Such coagulant can impede the flow of current from treatment electrode to tissue and thus must be removed to allow effective energy delivery to tissue.

Figure 5 illustrates the steps of a method for using the above described instrument. After adequate cervical dilation, preferably with a balloon cervical dilator, the resectoscope is inserted 170, an isotonic distension fluid, such as saline or Ringer's lactate is inserted 172. A continuous flow of isotonic fluid is applied 174 and the electrodes 176 are inserted through the first fluid channel 29. After visual identification 178 of the treatment site (myoma), the electrode assembly is immersed 180 in the

fluid adjacent to the treatment site to provide power to the assembly such that an electrical current can be passed through the treatment electrode. An electrical current is applied to cut 182 or treat the identified site. Tissue morcellation can be used while the electrode or loops of the resectoscope are moved by the operator to cut the identified section while monitoring fluid flow and adjusting as necessary. The loops can also be kept at a fixed distance from the resectoscope and drawn back like a curette. As the procedure progresses, the slices of tissue are deposited on the side to keep the field clear. Progressive enucleation of the deep interstitial part of the myoma can be obtained by massage of the uterus, hydromassage through a hysteromat to obtain a realignment of surrounding myometrium. Chips of tissues are collected by curettage and after removal 184, can be sent for pathological examination. The procedure can be repeated 188 to remove tissue from other sections. With adequately controlled irrigation and a properly blended high-frequency signal the procedure is generally bloodless and vision is clear throughout. Hemorrhage may occur when resection is too deep and reaches the deep subserous vascular bed. The electrodes are retracted 186 into first fluid channel and the probe and any excess fluid are removed. After the procedure the outer sheath can be disposed 190 while the remainder of the instrument is sterilized and reused.

When a large electrode, whether loops or rollers, makes contact with tissue for endometrial ablation or fibroid removal, coagulation and desiccation occur because the energy immediately spreads, resulting in a decrease in the power density. Low-power-density electrical energy use over a relatively long period of time can cause deeper tissue destruction than an equivalent amount of energy delivered at a high power density. This is because increased coagulation causes increased tissue impedance and

a consequent decrease in current flow. Deep destruction of greater than about 5 mm can be most effectively accomplished by using power of a continuous low-density waveform ('cutting current' at, e.g. <70 Watts). Tissue destruction can be slow, and therefore extremely difficult for the operator to gauge or control.

The operator presses the electrode gently into contact with the tissue and activates the current. A relatively large volume of tissue is destroyed and the electrode should be held in one spot as long as required until blanching is observed around the electrode (less than about one second).

When blanching all around the electrode has been observed, the operator can move the electrode slowly toward the cervical canal. To determine how rapidly the electrode should be moved, the operator must watch the zone of visible tissue destruction preceding the electrode. A relatively high level of power is required to pass through the desiccated tissue and coagulate tissue in front of it. Low-wattage 'coagulation current' best balances the need for surgical speed. Different electrosurgical units vary in the amount of wattage they provide; however, 70-110 Watts usually will provide sufficient energy to cause the desired level of destruction. The operator should begin at a low power and work up as needed.

After the operator presses the charged electrode against the uterine wall, blanching is visible around the electrode within one second. If no visible effect is observed, the power setting should be increased. If rapid, excessive cutting is present, the power setting is too high. At the appropriate power setting, the electrode is rolled slowly toward the optic. The operator should be able to see the coagulation zone preceding the electrode. As the electrode progresses beyond the original area of coagulation, only the advancing edge of the electrode

contacts as-yet-uncoagulated tissue. The rest of the electrode is passing over already coagulated tissue, where the current is impeded by the previous coagulation. This allows reduction in time of exposure, and therefore, forward motion of the electrode. An important aspect of the surgery is that the operator maintains a steady, but slow pace in moving the electrode over the surface.

Irrigation can be electronically controlled to optimally control liquid flow and pressure to reduce the risk of intravasation. Liquid used is controlled by positive pressure thus monitoring the amount of liquid used.

A high-frequency current properly blended between cutting and coagulation effects allows precise electrosection without carbonization yet with adequate control of bleeding. It is critical to properly employ the electrosurgical device to avoid the risk of accidents that may include inappropriate stimulation of adjacent muscles and nerves or burns and arcing.

Another preferred embodiment of a bipolar electrosurgical system employs an electrode assembly 101 illustrated in Figure 6. In this embodiment, a single loop 102 or cutting edge is connected to a single rigid wire 108 to provide the delivery electrode. The portion of the wire 108 proximal to the loop 102 is covered with an insulator 106 and a return electrode 104 is formed on the insulator 106. The return electrode in this embodiment preferably has a surface area substantially larger than the surface area of the cutting electrode to improve operating efficiency. The return electrode is connected along second insulated conductor 103 to lead 30 emerging from cuff 48 as shown in Figure 1A and is connected to the generator. A stabilizer ring 105 is used to position the electrode assembly 101 relative to the viewing optics. The electrode assembly in this and other embodiments described herein can

be positioned at an inoperative position within the sheath and moved between the inoperative position and the operative position shown.

In another preferred embodiment, a single loop is used as shown in Figure 6, except that the return electrode is the inner sheath 19 of Figure 1C. Alternatively, the outer sheath 17 can also be used as the return electrode. In these embodiments, the outer sheath 17 or inner sheath 19 is a conductive metal such as stainless steel that is connected at the proximal end to the external assembly using an insulating ring, and a conductive bushing connects the sheath to a lead attached to the generator. The inner and/or outer walls of the sheath can be coated with an insulating material leaving a distal portion of the metal sheath exposed.

In another preferred embodiment, a return electrode of the bipolar system extends along an inner and/or outer surface of a sheath that is concentric about the electrode assembly. In this embodiment, as illustrated in Figure 7A, the external sheath 100 is a non-conductive material with an insulated conductive wire 107 or metallized strip extending from each electrode at the distal end 106 of the sheath 100 to a terminal connector 108 at the proximal end 110 of the sheath 100. The proximal end 110 is attached to a hub assembly housing 112 that couples the insertable portion of the sheath to the handle section 38 of the device. A back pressure seal 114 is used at the proximal end 110 to provide a fluid seal between the sheath 100 and the housing 112. To prevent axial or rotational movement a locking mechanism 115 rigidly connects the housing 112 to the outlet port section 47. The connector 108 within housing 112 electrically connects wires 107 to an external wire connected to a safety circuit as described below, or can electrically connect wires to a connector 135 on the outside wall of housing 112.

As seen in the cross-sectional view of the distal end of the device shown in Figure 7B, the beak 37 is connected to a sheath as illustrated in Figure 1B and is surrounded by sheath 100. Along a distal section of the sheath 100, an opening 105 in the sheath extends axially and an electrode assembly having two electrode elements 121, 122 are on opposite sides of the opening. Each element 121,122 can extend around an edge of the opening so that both the inside wall of the sheath and the outside wall of the sheath are partially covered by the electrode elements. Electrodes 121,122 are connected by separate wires 107 to connector 108. In one embodiment, electrode element 121 is a positive electrode and electrode element 122 is a negative electrode as described in connection with Figure 10 below. The sheath 100 is a rigid dielectric material and serves as a disposable component of the device. Another dielectric shrink cover extends around the sheath 100 to insulate each conductive wire 107.

A preferred embodiment for the hub assembly that connects the disposable sheath 136 to the handle section 130 is illustrated in Figure 8. A reusable fitting 132 is threaded internally on both sides to attach to external threading of section 130 in which the flow connector 46 is situated, and to attach to external threading 140 on the proximal end of sheath 136. The outer sheath 136 slides over inner sheath 19 and defines the channel 31, as seen in Figure 1C, through which fluid returns and exits through port 134 in fitting 132.

The return electrode can be connected to a generator with connector lead 135. Section 130, fitting 132, housing 140 and sheath 136 are connected to form a common coaxial pathway 138 through which fluid and other system components are inserted. The sheath can have two electrodes positioned on opposite sides of the assembly which can both be connected to the generator.

Another preferred embodiment of the invention utilizes the inner sheath 19 as the return electrode where a conductive metal contact 137 or bushing is mounted on a small area of the inner wall 139 of the disposable sheath 136. This embodiment is illustrated in greater detail in connection with Figure 9. The contact 137 can be spring mounted to inner wall at 139 to engage the conductive metal outer surface of sheath 141. Several such contacts can be used around the sheath 141 to improve contact and center the sheath without disrupting fluid flow. The inner sheath 141 can be partially insulated from the fluid medium with an insulating liner 143,145 on the inner and/or outer wall of sheath 141, respectively. The insulating liner 145 has openings to provide contact area(s) for the contact(s) 137.

As illustrated in Figure 10 the insertable portion of sheath 136 can include a distal section 106 having a treatment electrode 156 and two electrode elements 152,154. Generator 158 provides the signal used for treatment. Second generator 162 is part of a safety circuit 160 that applies a separate signal across electrodes 152,154 to detect whether the distal section 106 is immersed in solution. Detector 164 senses whether there is a circuit through the solution at the distal section 106 so that treatment can be rendered safely. The detector generates a signal that enables the user to actuate generator 158 and proceed with treatment.

Illustrated in Figure 11 is another preferred embodiment of an electrosurgical probe in accordance with the invention. In this embodiment an existing device 214 includes ports for inflow 222 and outflow 216, an inner channel with beak 209 attached at the distal end of an inner tube and an outer tube extending around the inner tube and having fluid inlet openings or holes 210 that provide fluid communication with port 216.

Extending over the outer tube and attaching to the fluid port 216 is a sheath assembly 200 including the insulated electrode sheath 201 and the hub assembly 204. The hub assembly, described in greater detail below, can have a plurality of elements including a first section 206 coupled the sheath 201 and a second section 205 that couples the sheath assembly to the existing assembly 214.

The sheath 201 includes a metal tube that is covered or coated on the outer surface by a layer of insulating material 208. The metal tube is exposed at area 218 to provide the exposed return electrode region. The inner surface of the tube is covered completely with an inner insulating layer 220 that extends distally from the electrode region 218. The electrode region 218 has an aperture 215 to expose openings 210.

The hub assembly is shown in greater detail in the top view of Figure 12. A latch or arm 230 is attached to section 205 at a pivot 232. The arm 230 rotates around pivot 232 using manually actuated handle 212 such that curved surface 226 of arm 230 extends around port 216 when in a holding position. The arm 230 can be held in the holding position by spring 228. The user rotates the arm into a release position which rotates surface 226 from the port 216 to permit separation of the assembly 200 from the device 214. The electrode surface 218 is connected to the generator by wires 207 which are connected to the distal end of the metal tube.

As illustrated in Figures 13A and 13B, the metal tube 211 has an exposed region 218 and an outer surface covered by insulator 208. The tube 211 extends around the outer tube 203. The tube 211 can have an opening 234 that provides some radial flexibility and permits the assembly to slide over an outer tube 203 that protrudes slightly at the distal end at openings 210 to more readily accommodate fluid flow through the openings.

In another preferred embodiment, the hub assembly 204 is replaced by the system illustrated in Figures 14A-14D. In this embodiment, a connector 250 is used to attach the sheath assembly 200 to an existing device 214 in which the connector frictionally engages the outer tube 203. A preferred system for frictionally engaging the tube can include an outer housing 254 with a central opening 255 through which tube 203 is inserted.

Within housing 254 is an inner ring 256 that can be moved from a first or open position, shown in Figure 14A, to a second or closed position, shown in Figure 14B. In the open position, the inner ring 256 has a central opening that is aligned with the opening 255 of housing 254. In the closed position, a surface 262 of the inner ring extends through a small portion of the opening 255 to reduce the diameter of the opening. When the tube 203 is inserted through opening 255 and the ring 254 is moved in the closed position, the surface 262 engages the outer surface of tube 203 along with inner surfaces 257 of housing 254 to frictionally engage the tube.

Movement of the ring 256 or engaging member relative to housing 254 to grip the tube 203 can be accomplished using a lever 252 that pivots along axis 261 relative to housing 254. The lever arm 252, as shown in Figure 14C, is attached to a connecting arm 260 that is attached at one end to lever 252 at axis 265 and is attached at a second end to ring 256 at axis 263. As the ring 256 is attached to the housing 254 at axis 267, closing of the lever 254 causes the ring 256 to move and "snap" into a locked position.

As shown in Figure 14D, the sheath 201 extending over outer tube 203 can be attached to a first section 270 of the hub assembly. Section 270 is secured to element 250 as described previously which locks to frictionally grip tube 203 adjacent to existing unit 214. Alternatively, the

sheath 201 can be attached to element 250 and element 270 can be attached to the proximal side of element 250 with connecting leads or wire 264 extending from the joint between elements 250 and 270 such that it does not interfere with lever 252 operation.

The connector 250 can be used to connect to a number of different commercially available electrosurgical probes of a given size without modification of the existing probe or the sheath assembly. Two such existing devices are illustrated in connection with Figures 15A and 15B.

In Figure 15A, outer tube 203 with attached ports 216, 222, are shown partially separated from inner tube assembly 275. When knurled ring 274 abuts element 284 and is coupled to assembly 275, seals are formed at 0-ring 286 and between openings 280 and inner tube 282 such that fluid can be directed through port 222 and openings 280 to direct fluid through inner tube 282. Fluid is returned in the gap between tubes 282 and 203 and out through port 216.

In Figure 15B, the inner tube 304 is coupled to assembly 300 with inflow tube 302, and outer tube 303 is coupled to connector 310 with outflow tube 305.

In the embodiments of the invention illustrated in Figures 16A and 16B, the outer tubes 203 and 303 and their attached components are removed completely and replaced by sheath assemblies 290 and 320, respectively. In these embodiments, the insulated electrode sheath 292 includes distal openings to provide for return flow of fluid in the gap between inner tubes 282, 304 and the sheath 292. The sheath also has an exposed return electrode surface 218 as described previously.

In the embodiment of Figure 16A, the assembly 290 includes the sheath 292 coupled to first hub assembly 297, which is attached to a second hub assembly element 298 with outflow port 291. Element 298 is coupled to the third assembly element or connector 250 including 0-ring or other

sealing element 294 that forms a fluid tight seal around tube 282. The connector 250 grips the tube 282 in a manner described previously and is also coupled to fourth element 296 with inflow port 293. Element 296 forms a seal with ring 286 when it abuts against fixture 284. The element 250 can be connected to element 296 by threading 295 or other suitable mechanical connection, or the various elements can be combined to form a unitary hub assembly.

In the embodiment in which element 296 can be detached from element 250, the remaining hub assembly 320 can be that shown in Figure 16B where the connector 250 simply grips inner tube 304. The wiring 299 is electrically connected in any of these embodiments to the proximal end of the return electrode.

As described previously, the sheath assembly can be an insulating tube with an insulating wire or metallized region to provide a conductive path between the return electrode at the distal end and the proximal end.

Alternatively, another preferred embodiment of the invention includes fabricating a sheath assembly from a shaped metal tube such as a stainless steel element approximately 1/500 inches thick having inner and outer plastic sleeves (polycarbonate) that have been bonded to the inner and outer surfaces of the rolled steel tube using a UV curing adhesive. Alternatively, the insulating layer can be sprayed, deposited, or vacuum coated on a tube, or the tube can be dipped. Such a coating can be a commercially available material known as PARYLENE. The tube used to replace the outer tube, as shown in the embodiments of Figures 16A and 16B, can have a thickness in the range of 1/250-1/125 inches.

Equivalents

While the invention has been particularly shown and described with reference to a preferred embodiment thereof,

it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

Claims

1. An electrosurgical probe comprising:

an electrode assembly having a proximal end and a distal end, the assembly including to a treatment electrode at the distal end that receives an electrical signal from the proximal end the electrode assembly further including a return electrode;

a first fluid channel within the probe that supplies a flow of fluid through an aperture at the distal end of the probe into a body lumen or cavity; and

electrical connector that connects the treatment electrode and the return electrode to a cable for connection to an external energy source.

2. The probe of Claim 1 further comprising an isotonic fluid that flows through the first fluid channel

3. The probe of Claim 1 further comprising sheath having a conductive metal to form the return electrode.

4. The probe of Claim 3 wherein the sheath comprises a dielectric material.

5. The probe of Claim 2 further comprising a fluid reservoir connected to the first fluid channel and containing the isotonic fluid.

6. The probe of Claim 2 wherein the isotonic fluid has an osmolarity in the range of between about 280 and 290 milliosmols per liter.

7. The probe of Claim 1 further comprising an optically conductive path extending within the probe from the proximal end to the distal end to view a surgical site within the body lumen.

8. The probe of Claim 3 wherein the sheath comprises a metal sheath having an insulating layer and a non-insulated region defining a surface of the return electrode.

9. The probe of Claim 1 wherein the sheath extends around a first inner sheath and a second inner sheath.

10. A method for connecting a detachable sheath to an electrosurgical device comprising:

providing an electrosurgical probe having an electrode assembly with a proximal end and a distal end, the electrode assembly conducting an electrical signal from the proximal end to a treatment electrode at the distal end;

providing a return electrode assembly and a connector assembly to couple the return electrode assembly to the probe;

positioning the return electrode assembly relative to the probe; and

coupling the return electrode assembly to the probe with the connector assembly.

11. The method of Claim 10 further comprising providing a treatment electrode having a loop and wherein the return electrode comprises an exposed metal surface on the sheath.

12. The method of Claim 12 further comprising providing a probe having an optical path and a camera coupled to

the optical path such that an image of a surgical site can be generated with the camera.

13. The method of Claim 10 further comprising providing an isotonic fluid which comprises, for example, an optically transparent saline solution.

14. The method of Claim 13 wherein the isotonic fluid has an osmolarity in the range of between about 260 and 295 milliosmols per liter.

15. The method of Claim 10 further comprising providing an RF signal generator connected to the treatment electrode and transmitting an RF signal through the treatment electrode with the generator.

16. A sheath for mounting on an electrosurgical device comprising:

an insulating tubular sheath having a distal end and a proximal end;

a return electrode adjacent the distal end of the sheath that is electrically connected to the proximal end along a conductive path;

a connector assembly attached to the proximal end of the sheath for attaching the sheath to an electrosurgical device, the connector assembly including an electrical connector conductively connected to the return electrode along the conductive path.

17. The sheath of Claim 16 wherein the return electrode comprises an external annular surface of the sheath.

18. The sheath of Claim 16 wherein the sheath comprises a metal tube having an insulating layer thereon, the insulating layer having an opening to expose a surface

region of the metal tube that defines the return electrode.

19. The sheath of Claim 16 wherein the sheath has an annular opening adjacent the distal end of the device through which fluid can flow.

20. The sheath of Claim 16 wherein the connector assembly has a manually operated latch to attach the sheath to an electrosurgical device, the latch having an open position and a closed position.

21. An electrosurgical device comprising:

an elongate probe element adapted for insertion within a patient's body, the elongate probe element having at least first and second cannulas defining a first, central lumen disposed within the first cannula and a second lumen that surrounds the first cannula, the probe element further having a distal end and a proximal end;

a first fluid channel extending within the probe element that delivers a flow of an isotonic fluid through an exit port at the distal end of the probe element;

a second fluid channel extending within the probe element that evacuates fluid through the probe element from an area adjacent an inlet port at a distal portion of the probe element;

an active, energy delivering electrode disposed within the probe element such that a tissue contacting portion thereof is adapted to operatively extend from the distal end of the probe element; and

at least one return electrode associated with the distal end of the probe element, the return electrode

being electrically insulated from the active, energy delivering electrode through the probe.

22. The device of Claims 21 wherein at least one return electrode is formed upon a distal end of a removable and replaceable annular member that is adapted to be disposed over a distal, outer wall of the second cannula.

23. The device of Claim 22 wherein the annular member is a sheath.

24. The device of Claim 21 wherein the sheath is conductive and, except for a distal end thereof, inner and outer walls of the sheath are coated with an insulating material.

25. The device of Claim 23 wherein the sheath is made of a dielectric material and at least one return electrode is disposed on the distal end thereof.

26. The device of Claim 25 wherein first and second return electrodes are disposed on the distal end of the sheath.

27. The device of Claim 21 wherein the active, energy delivering electrode is movable between an operative position in which it extends from the distal end of the probe element and an inoperative position in which it is disposed within the probe element.

28. The device of Claim 21 wherein the active, energy delivering electrode is disposed within the first lumen.

29. The device of Claim 21 wherein the first fluid channel extends within the first lumen.

30. The device of Claim 21 wherein the second fluid channel extends within the second lumen.

31. The device of Claim 21 wherein the active, energy delivering electrode includes, at its distal end, a semicircular loop.

32. The device of Claim 21 further comprising an electrosurgical generator in electrical communication with the first and second conductor elements, the first conductor element transferring electrosurgical energy from the generator to the active, energy delivering electrode.

33. The device of Claim 21 further comprising a reservoir of an isotonic fluid, the reservoir being in fluid communication with the first fluid channel.

34. The device of Claim 33 wherein the isotonic fluid has an osmolarity in the range of about 280 to 290 milliosmols per liter.

35. The device of Claim 21 further comprising an optically conductive path extending within the probe element between the proximal and distal ends thereof.

36. The device of Claim 21 wherein the device is a surgical instrument selected from the group consisting of an arthroscope, and endoscope, a hysteroscope, a laparoscope, and a resectoscope.

37. The device of Claim 35 further comprising a camera optically coupled to the optically conductive path.

38. The device of Claim 21 wherein the active electrode moves between a first position and a second position relative to the probe element.

39. An electrosurgical device comprising:

an elongate probe element for insertion within a patient's body;

means for directing fluid through the probe element; and

electrode means for delivering energy to a treatment site with the elongate probe element, the electrode means including a treatment electrode and a return electrode.

40. The electrosurgical device of Claim 39 further comprising a sheath, the sheath including the return electrode and attaching means for attaching the sheath to a tube of the elongate probe element.

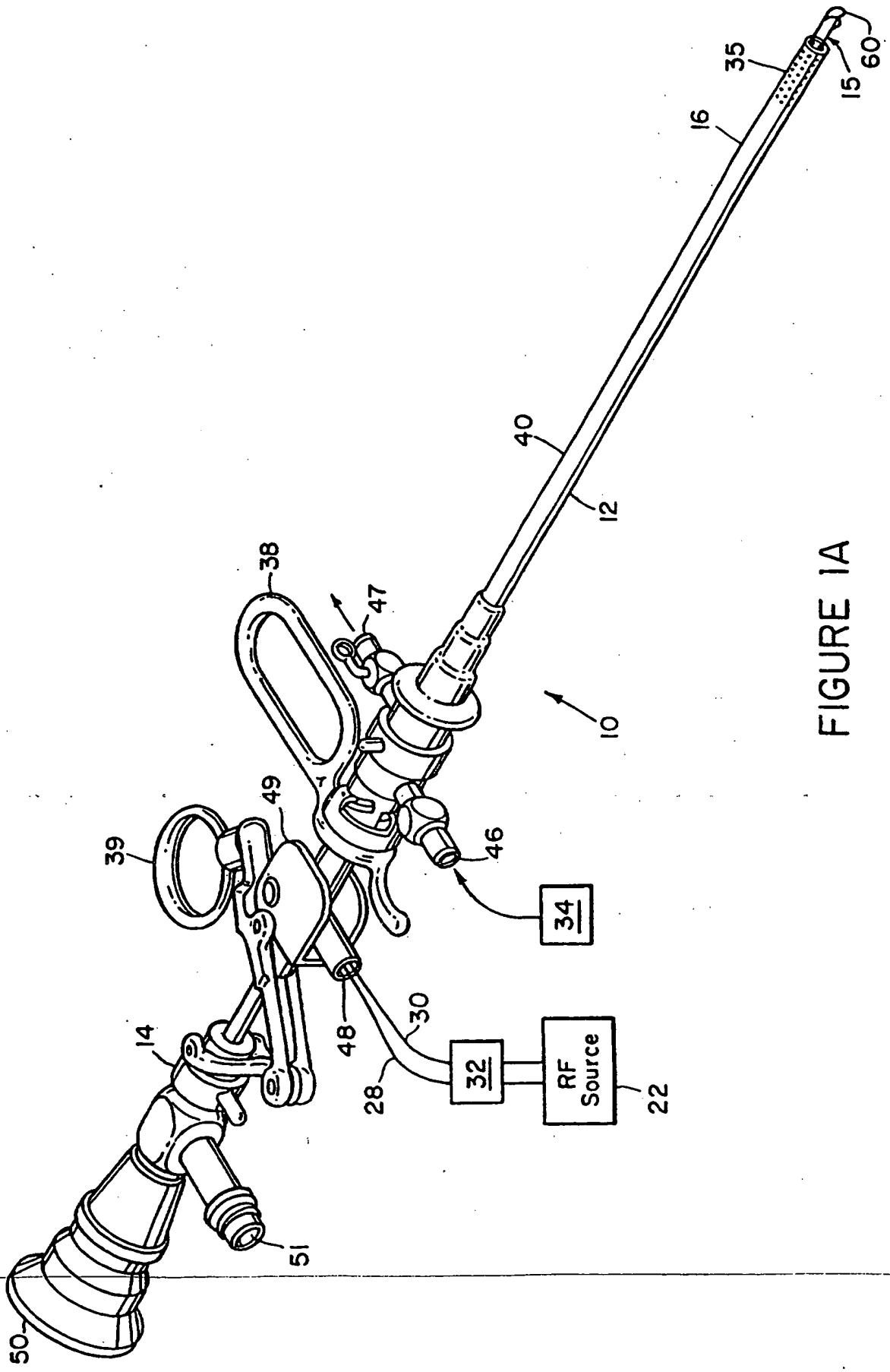
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FIGURE 1A

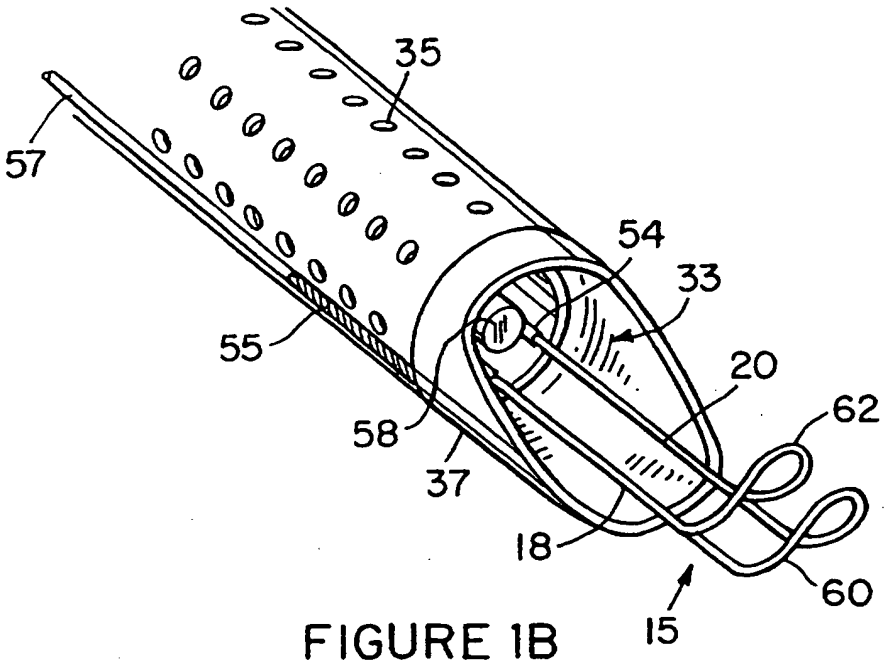

FIGURE 1B

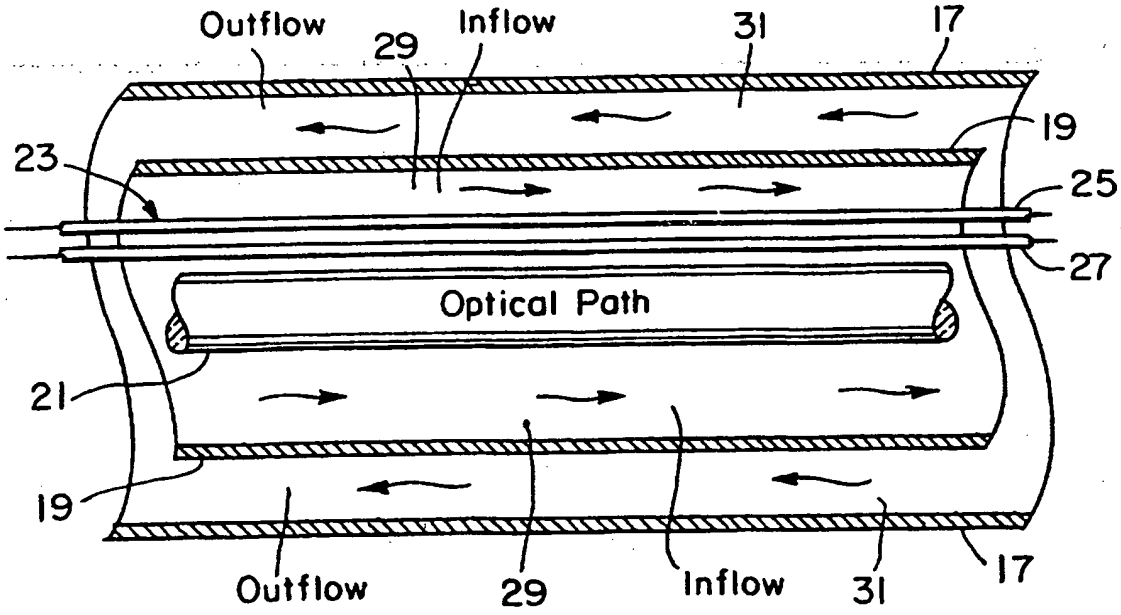

FIGURE 1C

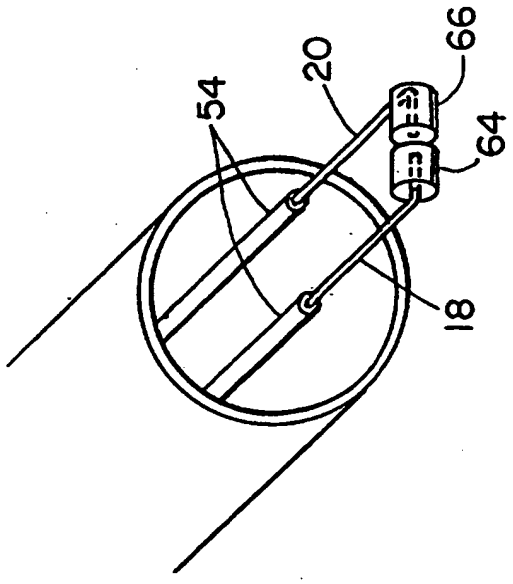

FIGURE 3

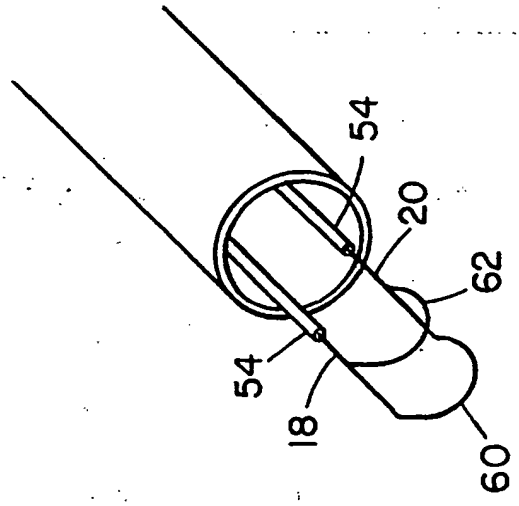

FIGURE 2

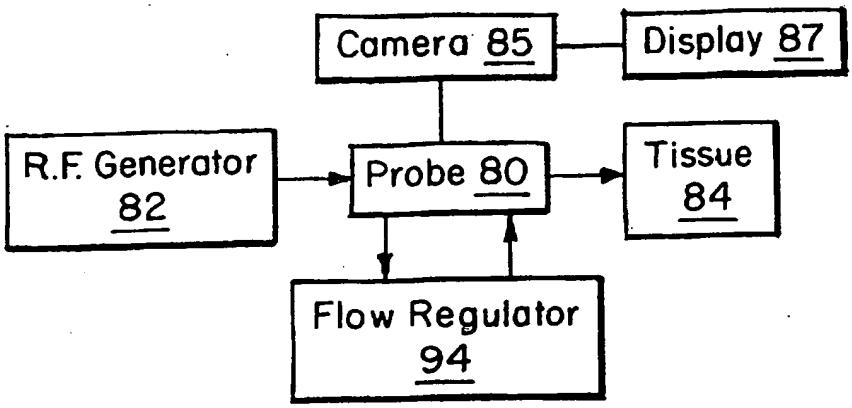

FIGURE 4

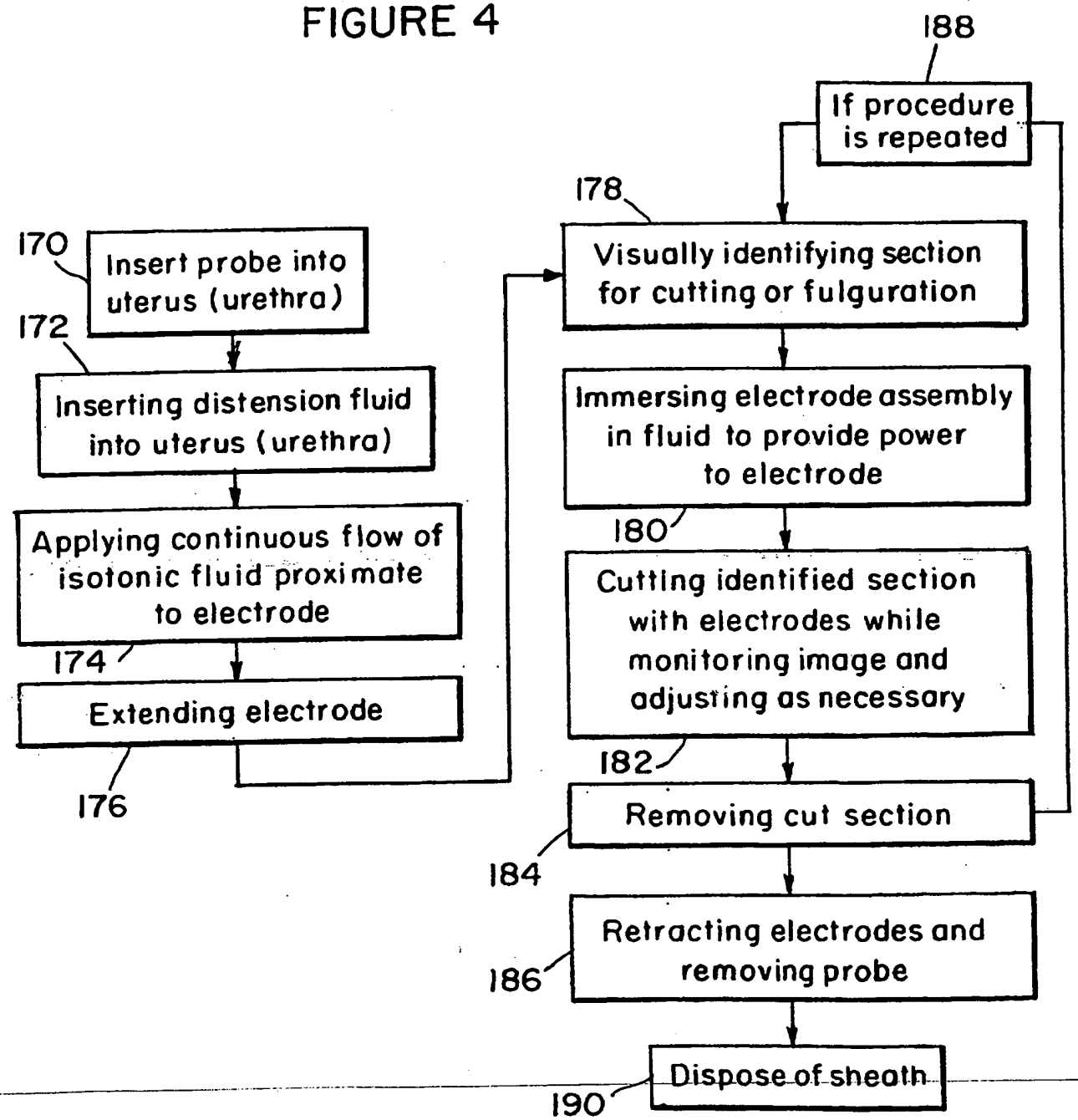

FIGURE 5

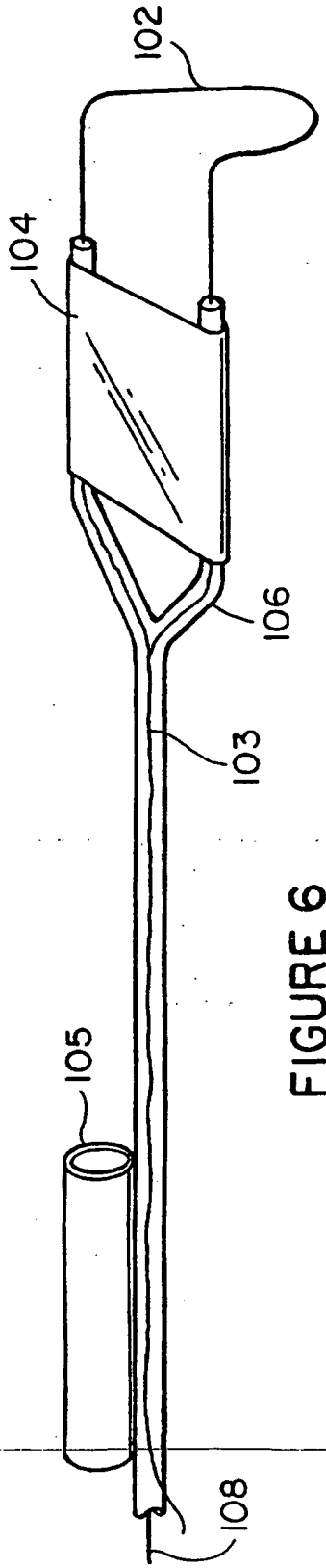

FIGURE 6

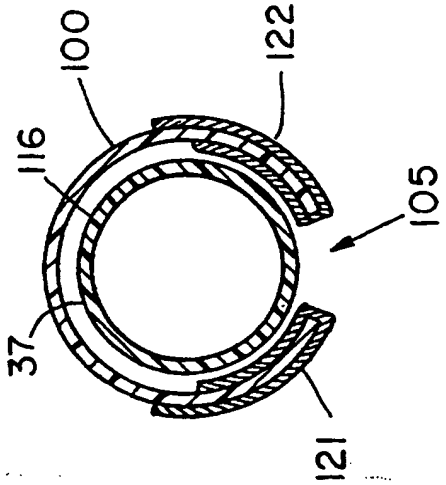

FIGURE 7B

FIGURE 7A

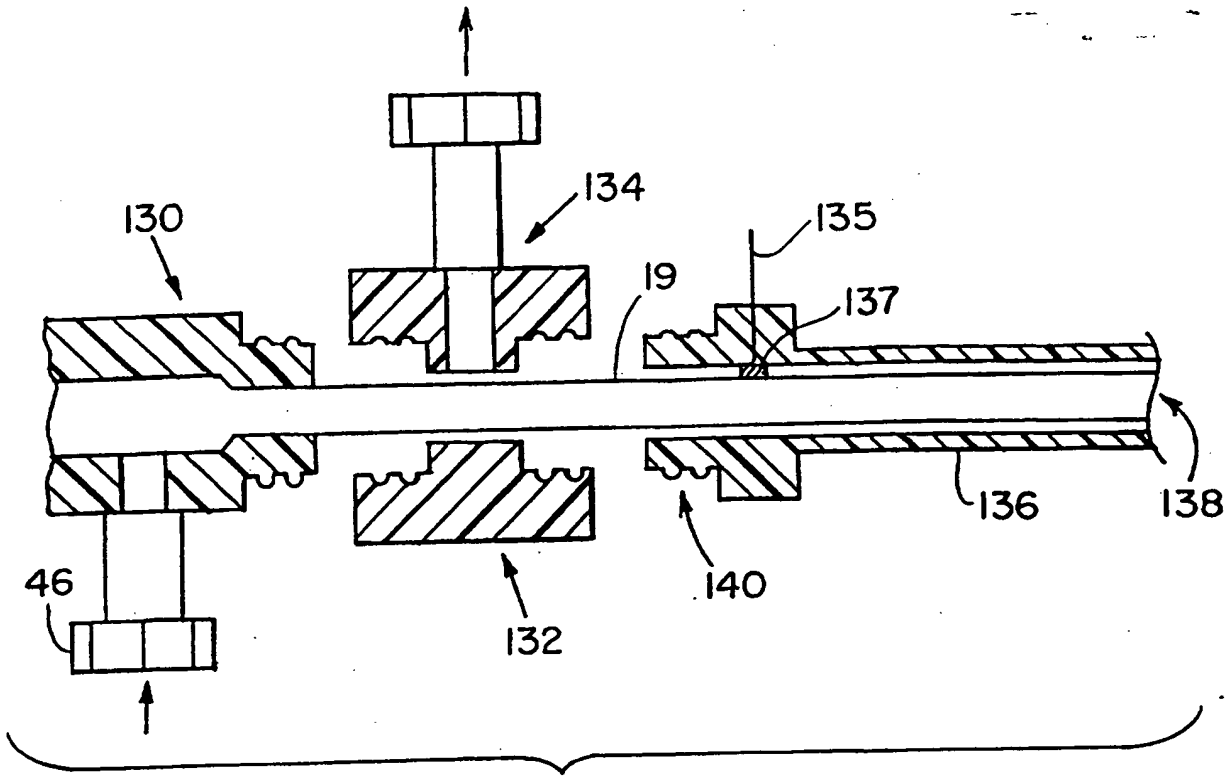

FIGURE 8

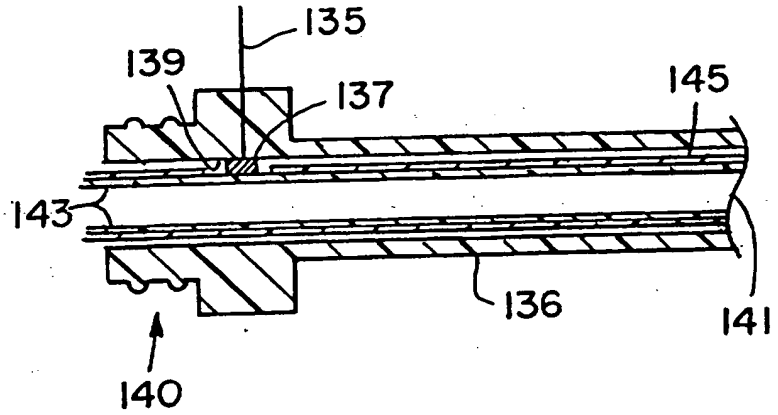

FIGURE 9

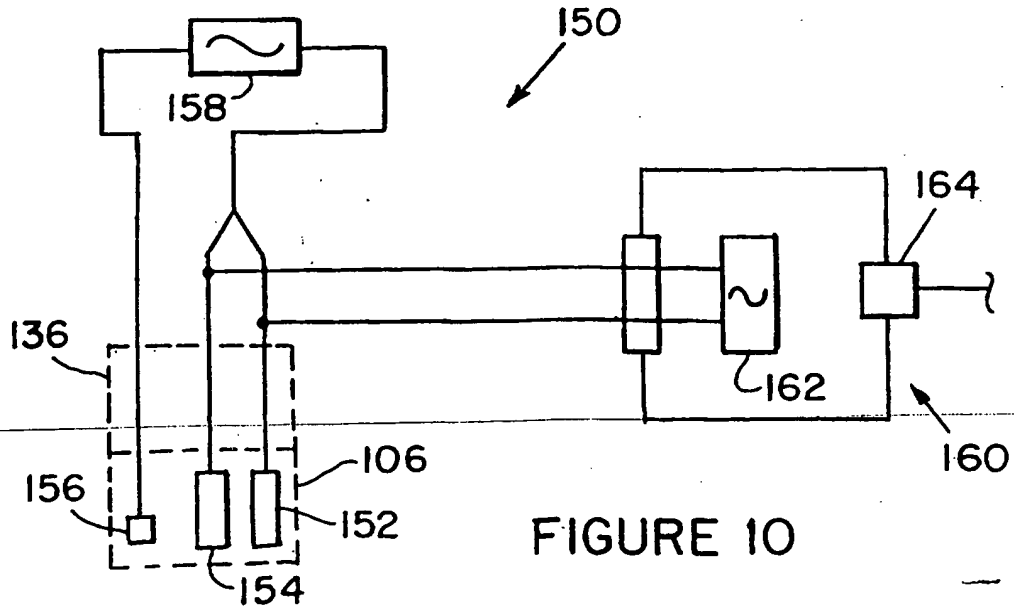

FIGURE 10

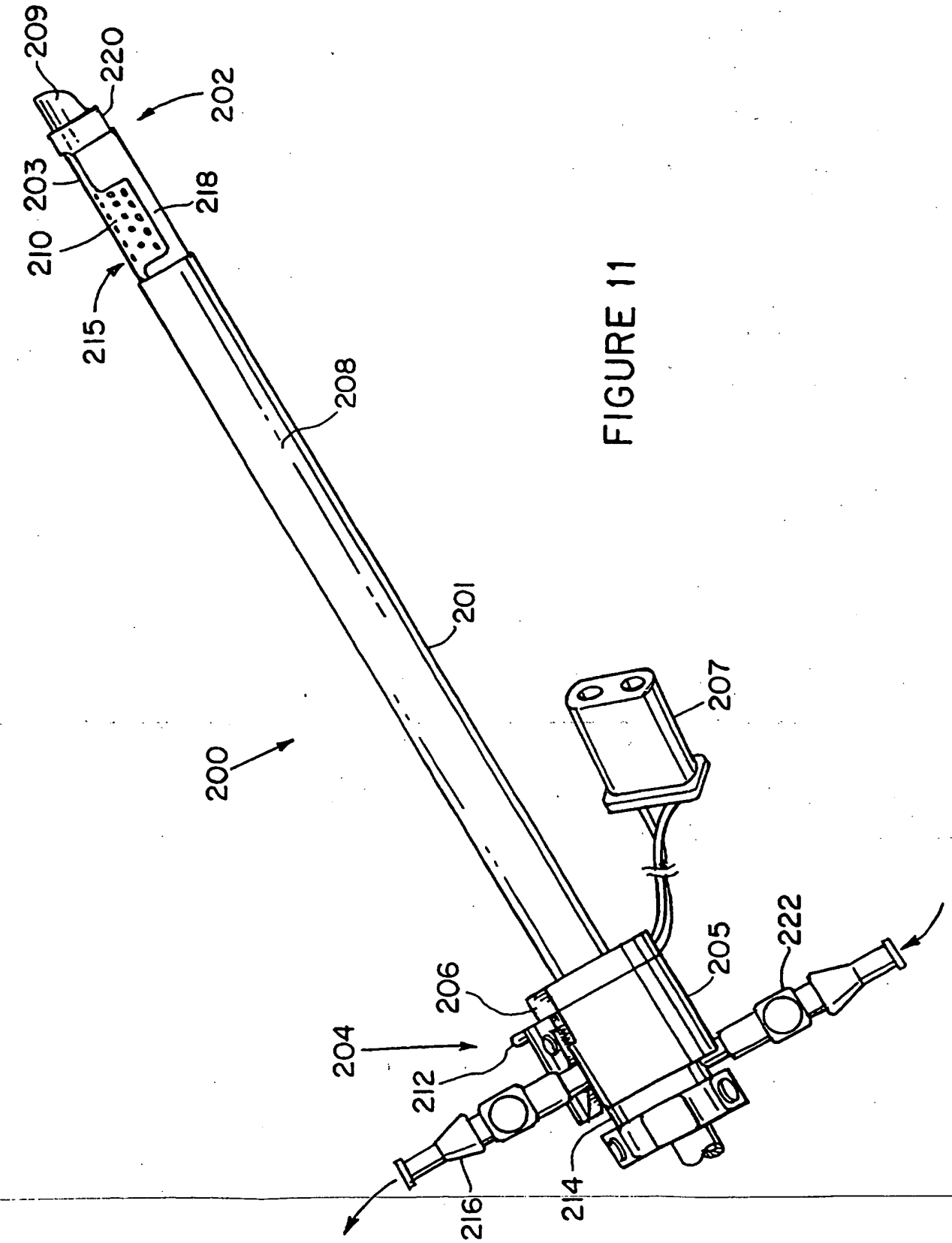
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FIGURE 11

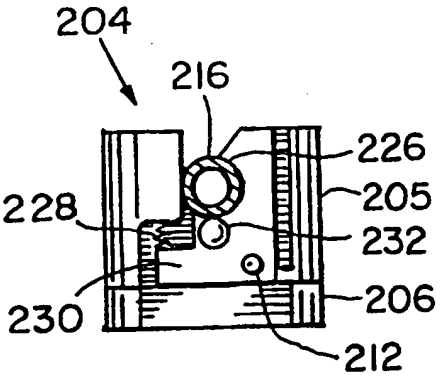

FIGURE 12

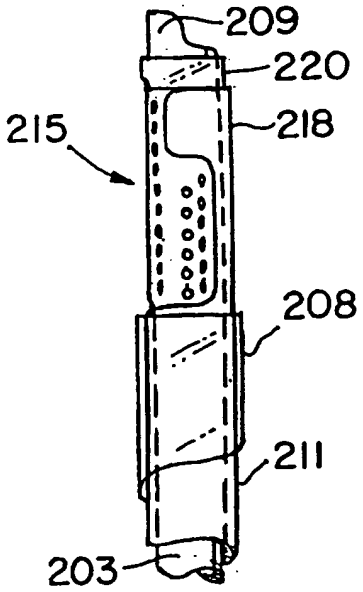

FIGURE 13A

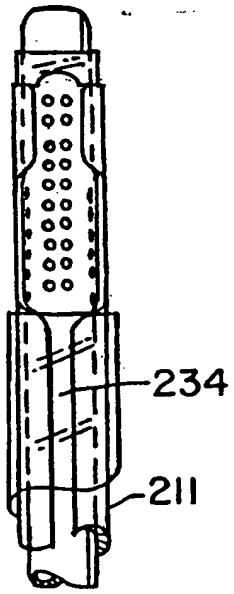

FIGURE 13B

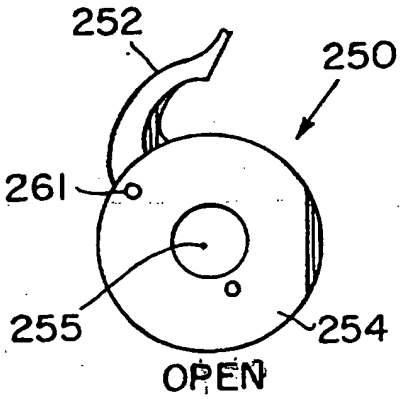

FIGURE 14A

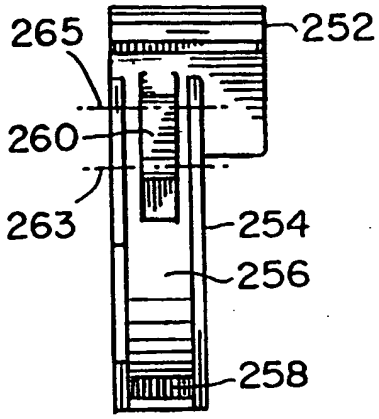

FIGURE 14C

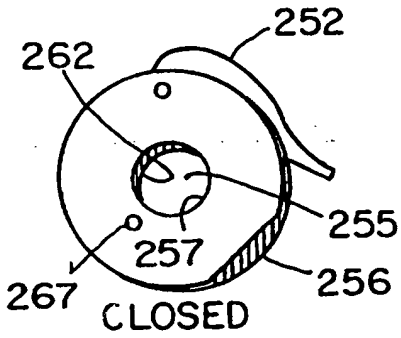

FIGURE 14B

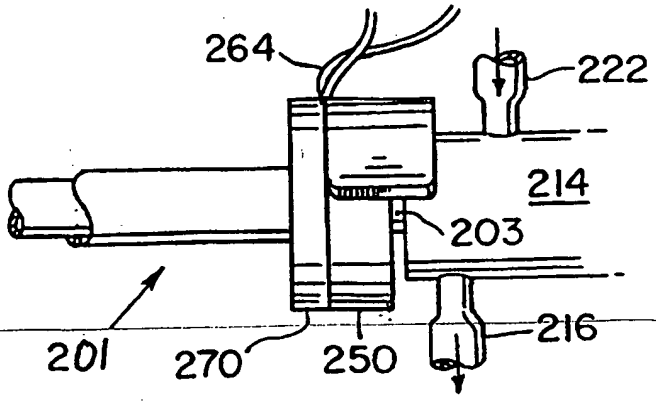

FIGURE 14D

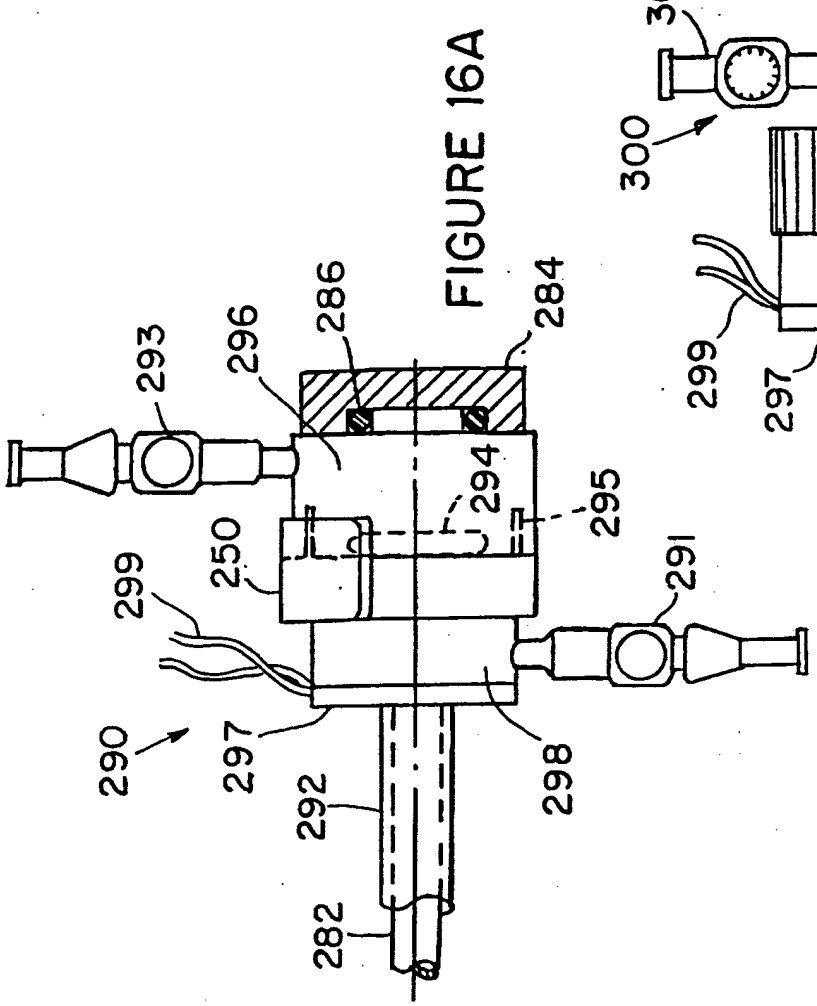

FIGURE 16A

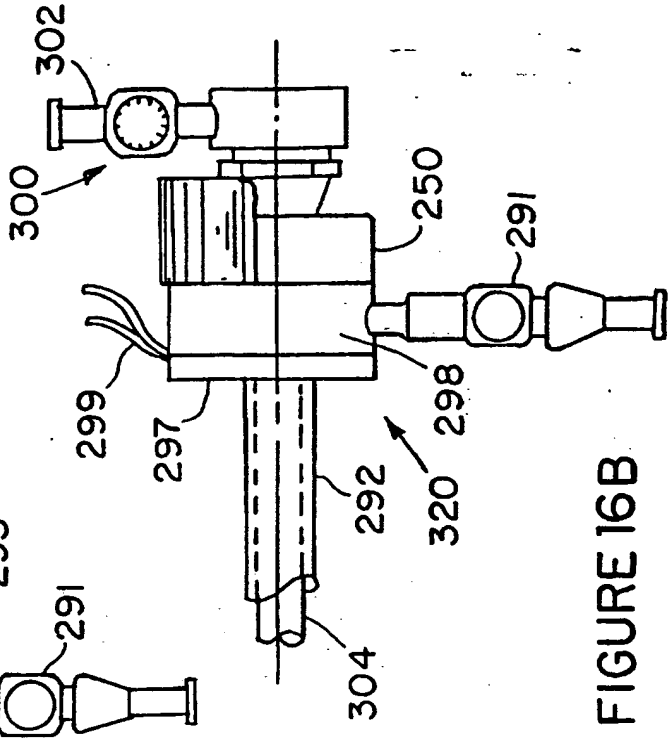

FIGURE 16B

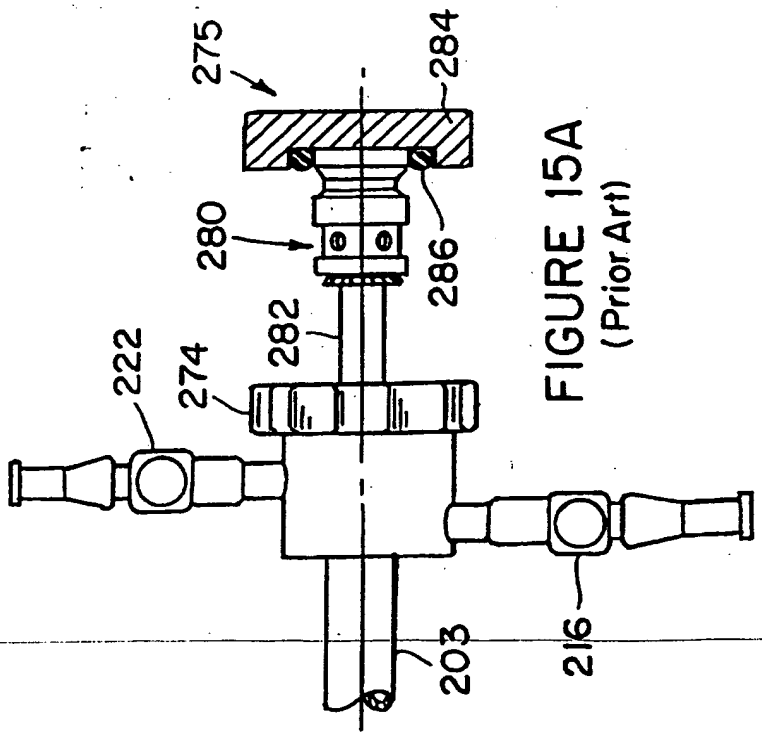

FIGURE 15A
(Prior Art)

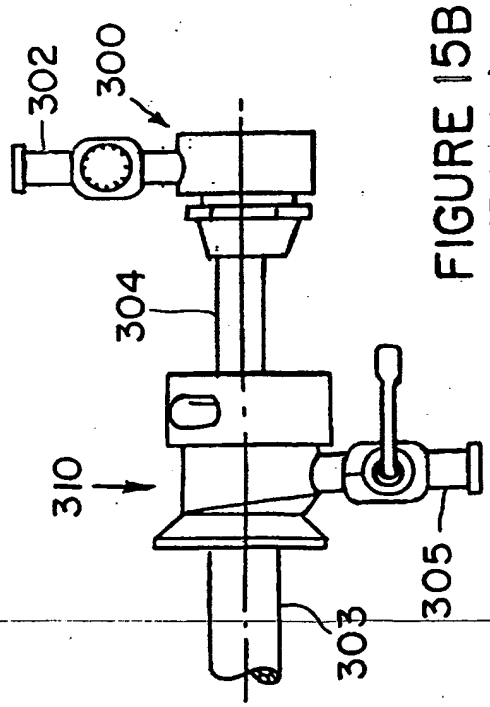

FIGURE 15B
(Prior Art)

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 96/20864

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE 25 21 719 A (DELMA ELEKTRO MED APP) 25 November 1976 see page 8, line 23 - page 9, line 20 see page 13, line 1 - line 28; figures 1,7,8	1-20, 22-26
Y	WO 94 26228 A (THAPLIYAL & EGGERS ;EGGERS PHILIP E (US); THAPLIYAL HIRA V (US)) 24 November 1994 see abstract; figure 1 see page 17, line 3 - page 18, line 12	1-20
X	US 5 401 272 A (PERKINS RODNEY C) 28 March 1995	21,27-40
Y	see abstract; figures see column 2, line 59 - column 4, line 35	22-26

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 May 1997	23.05.97
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Authorized officer Zeinstra, H

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 96/20864

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 34259 A (DESAI ASHVIN H) 21 December 1995 see abstract; figure 17 see page 8, line 22 - page 9, line 18 see page 11, line 37 - page 13, line 14 see page 17, line 15 - page 22, line 10 -----	21,27-40

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/US 96/20864

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 2521719 A	25-11-76	US 4116198 A	26-09-78
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		JP 9501328 T	10-02-97
US 5401272 A	28-03-95	US 5441498 A	15-08-95
WO 9534259 A	21-12-95	US 5562703 A	08-10-96
		AU 3137495 A	05-01-96

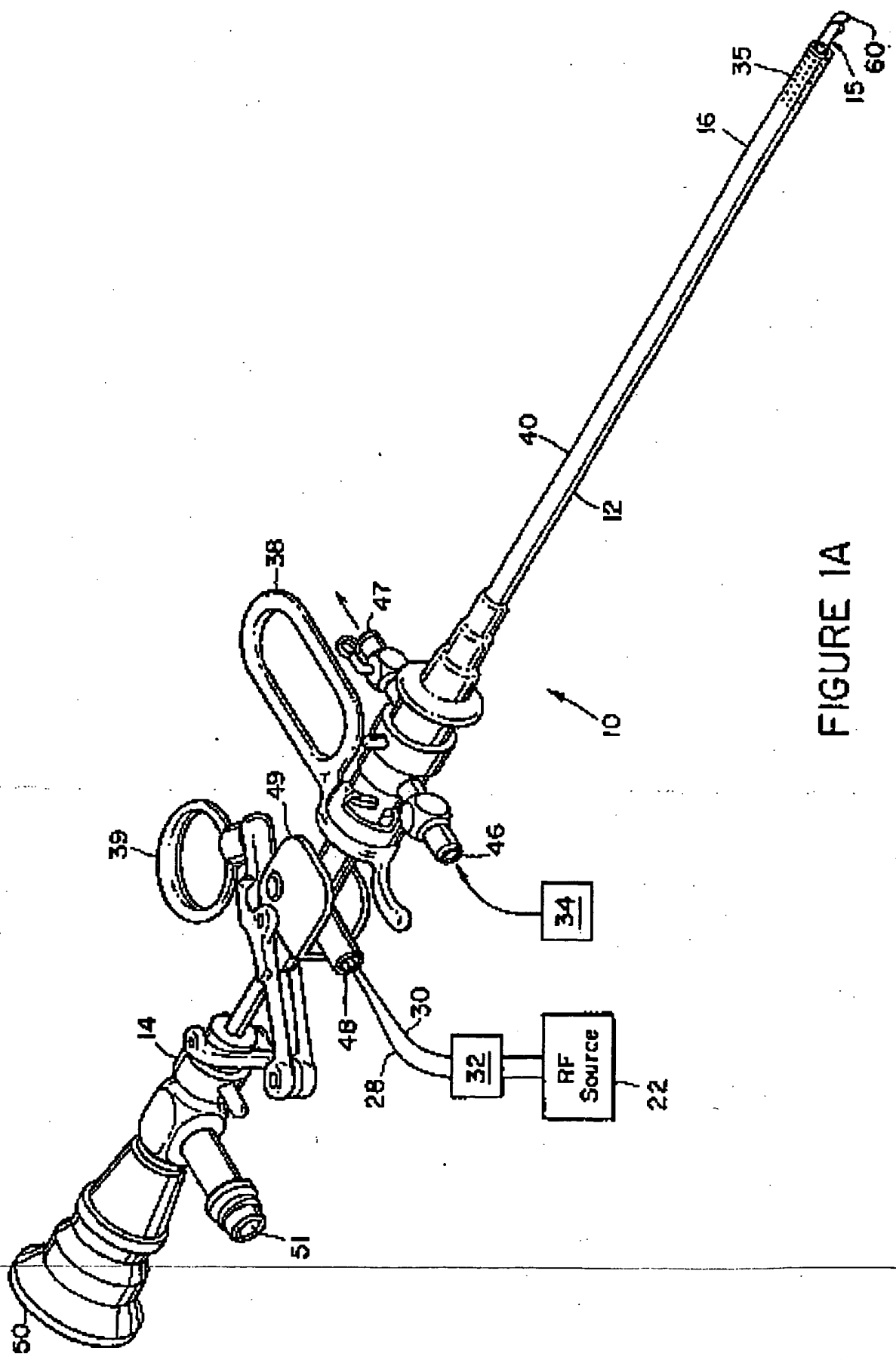
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FIGURE 1A

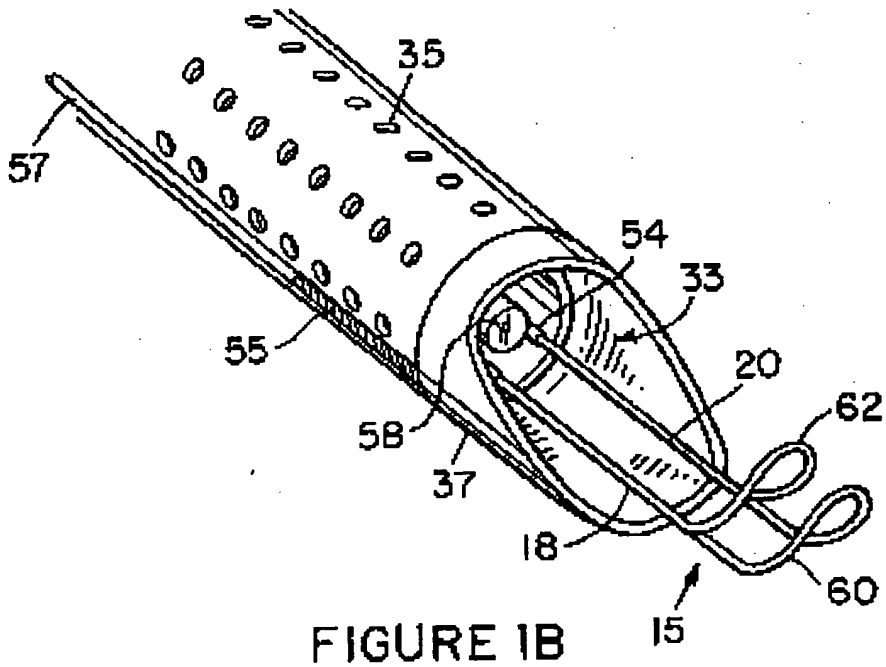


FIGURE 1B

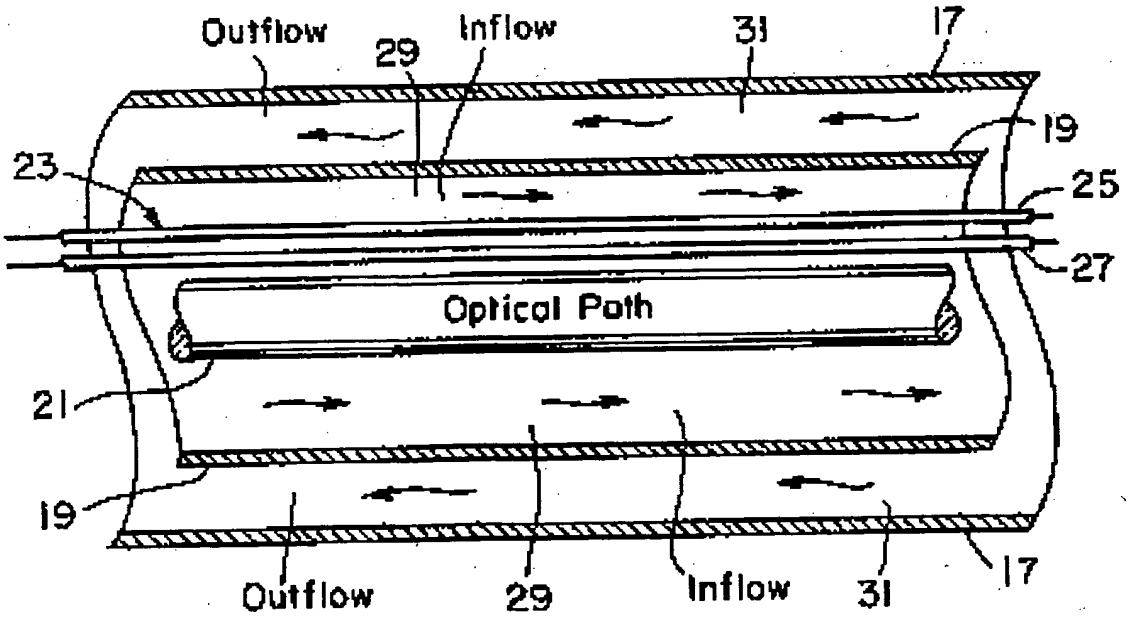


FIGURE 1C

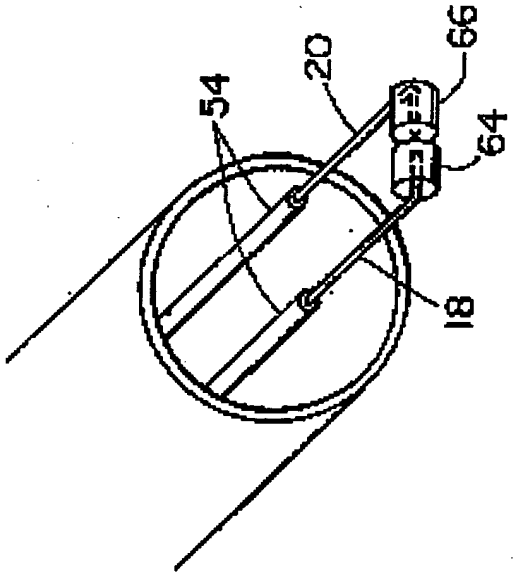


FIGURE 3

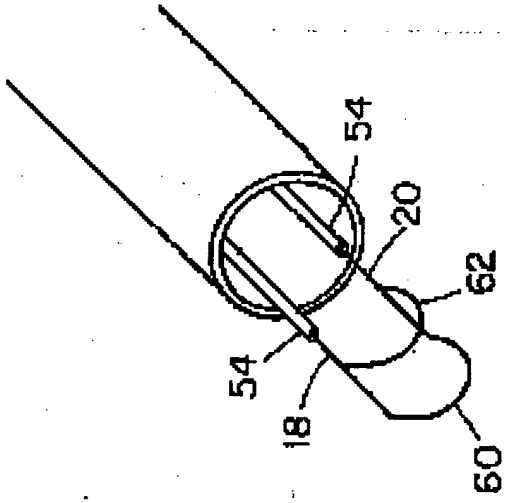


FIGURE 2

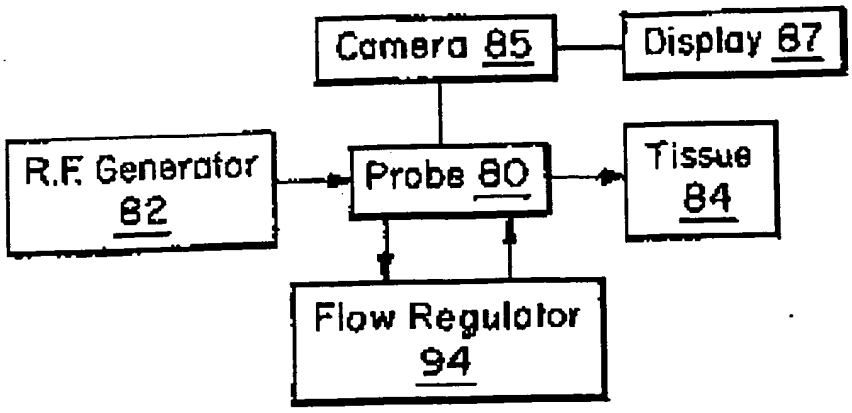


FIGURE 4

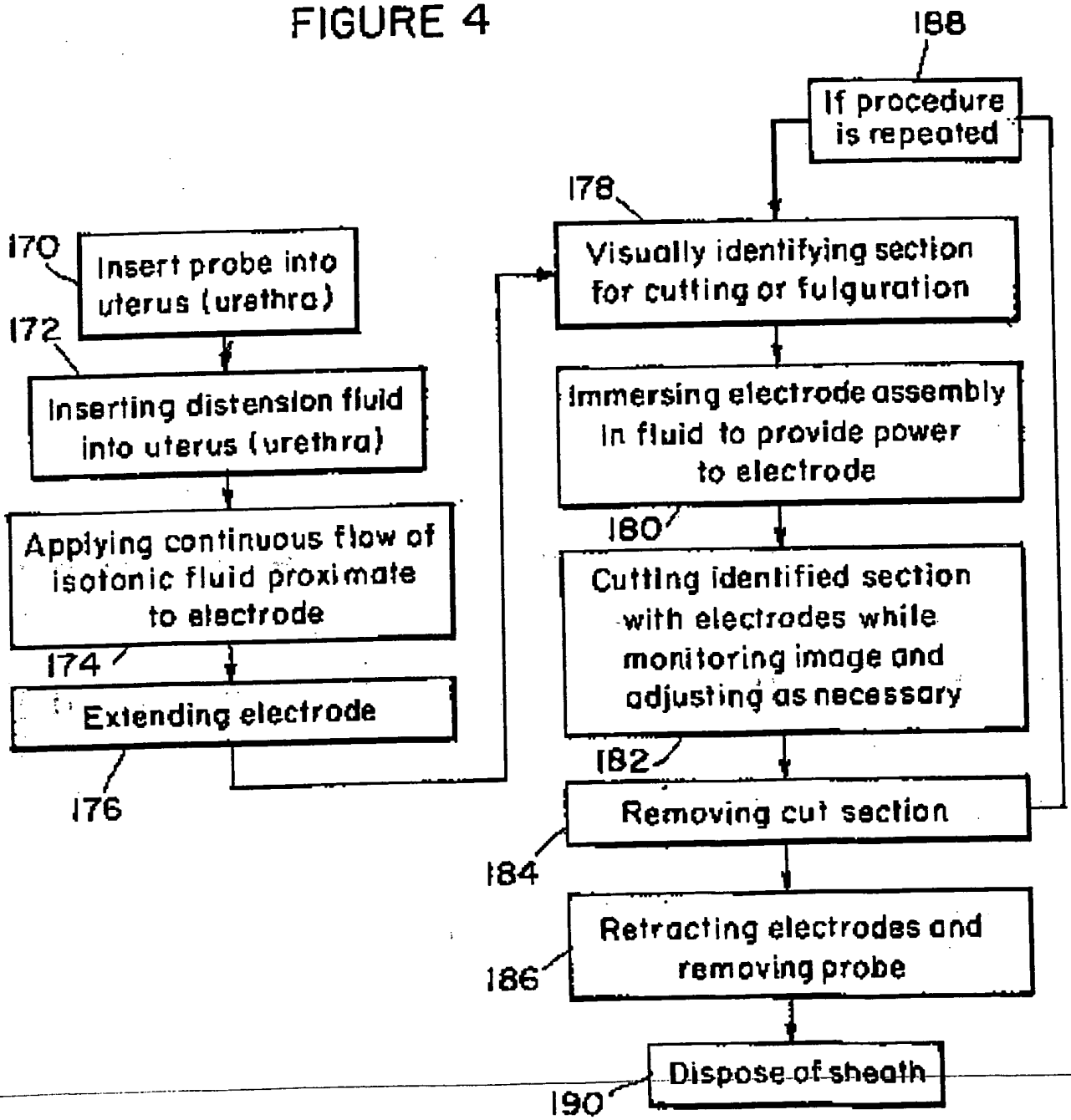
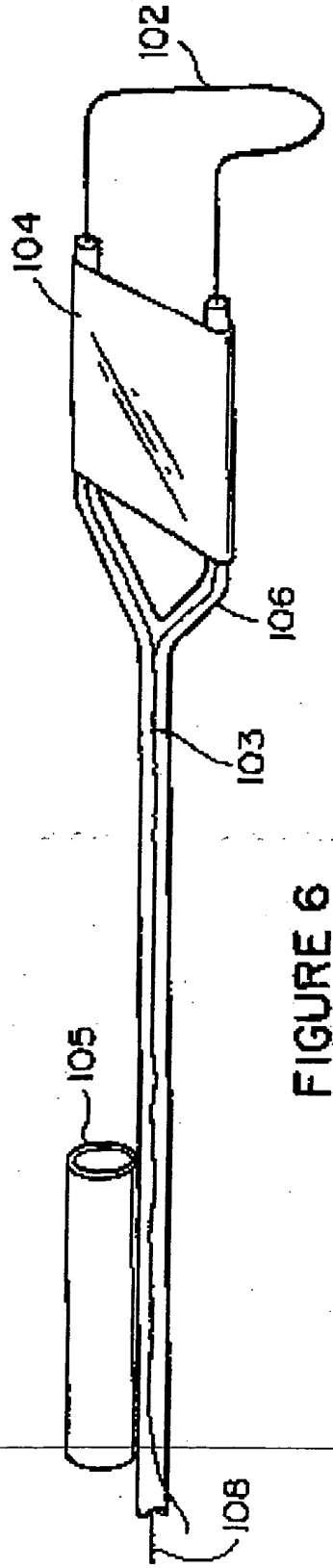


FIGURE 5



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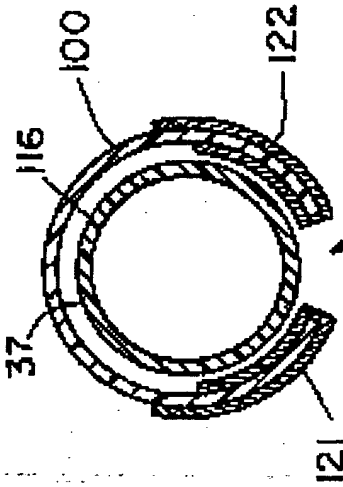


FIGURE 7B

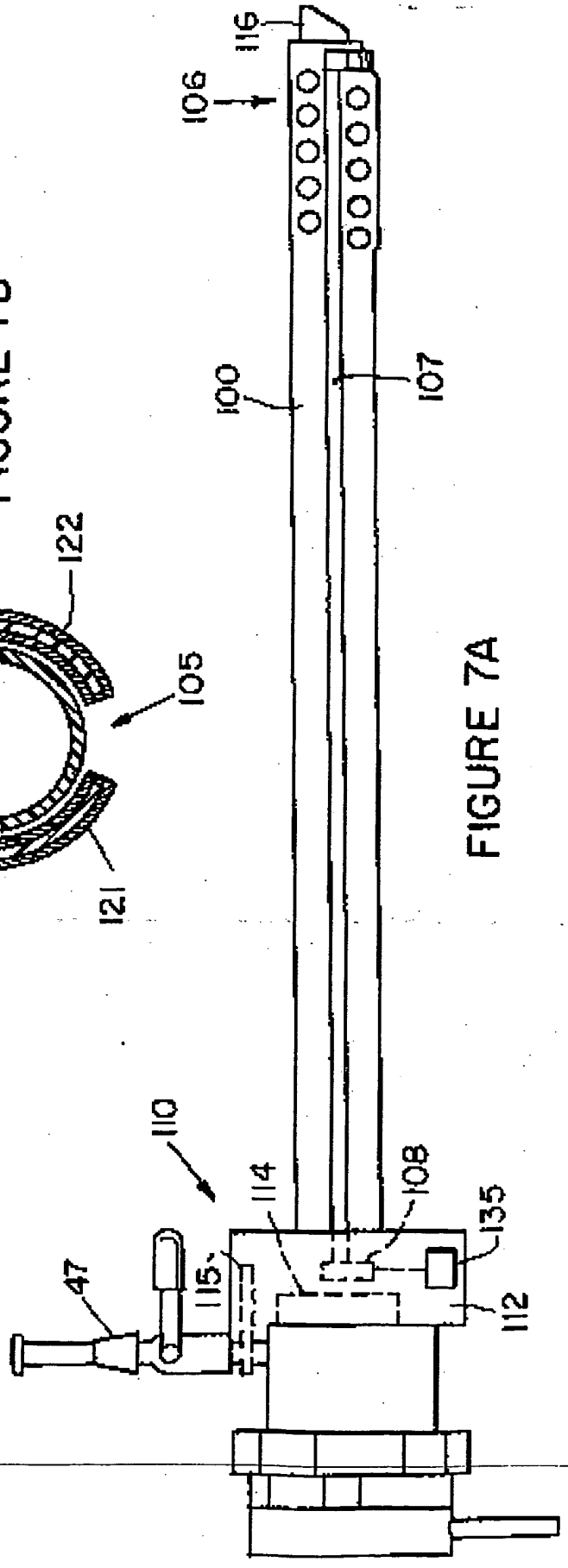


FIGURE 7A

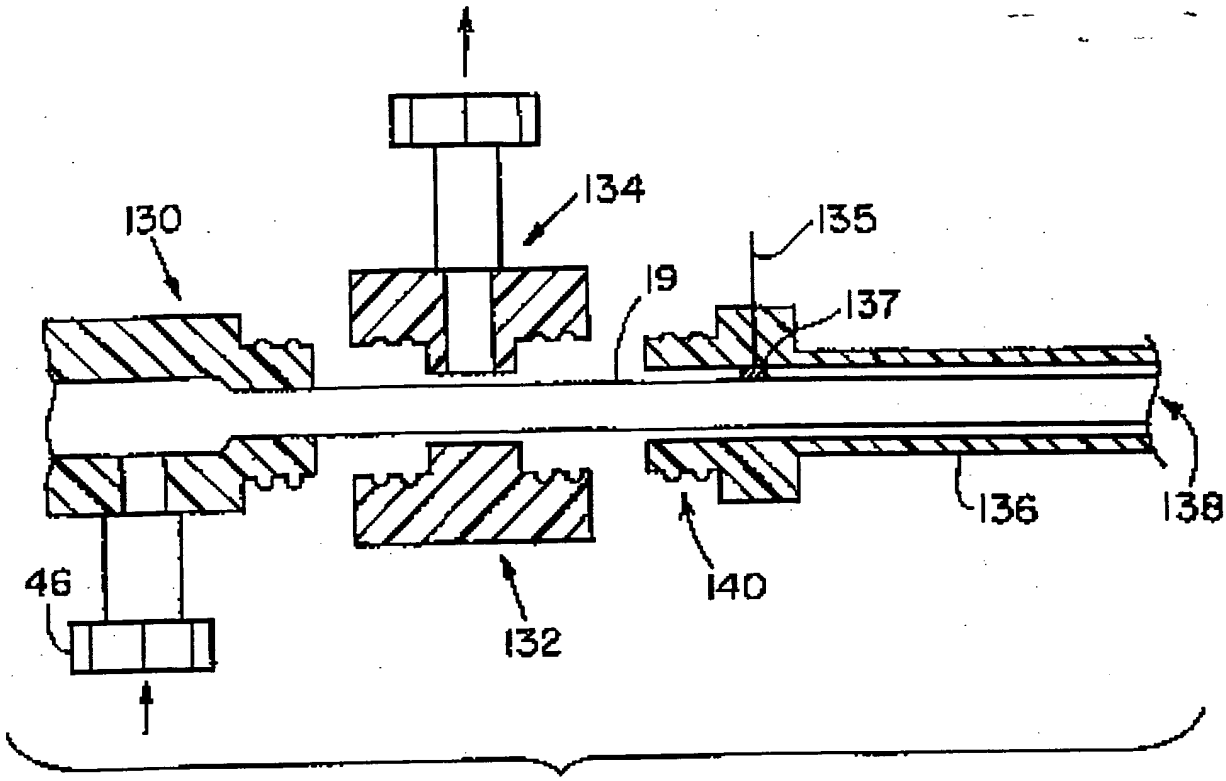
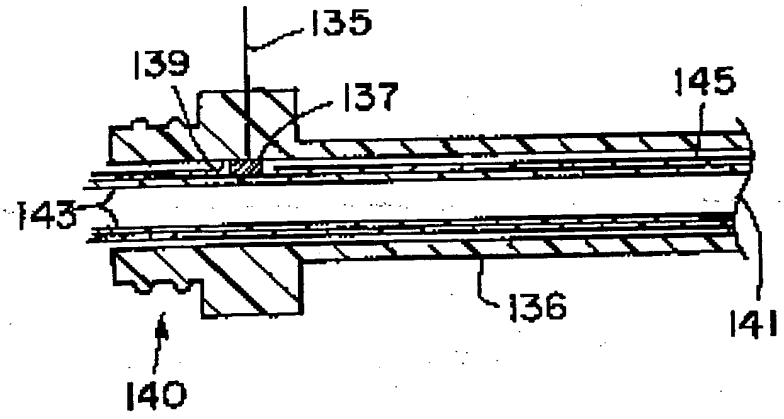


FIGURE 8



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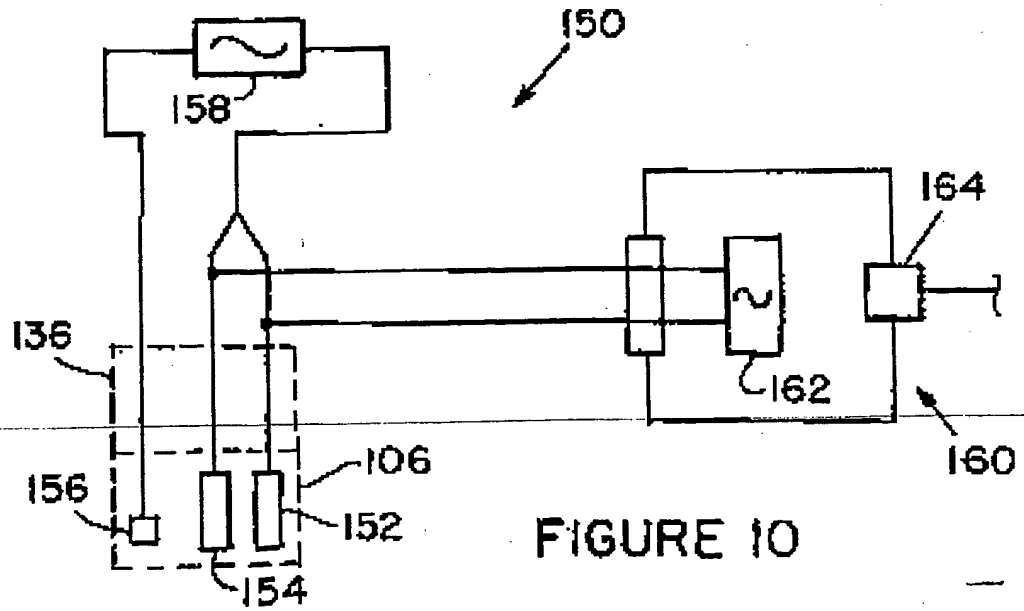

FIGURE 10

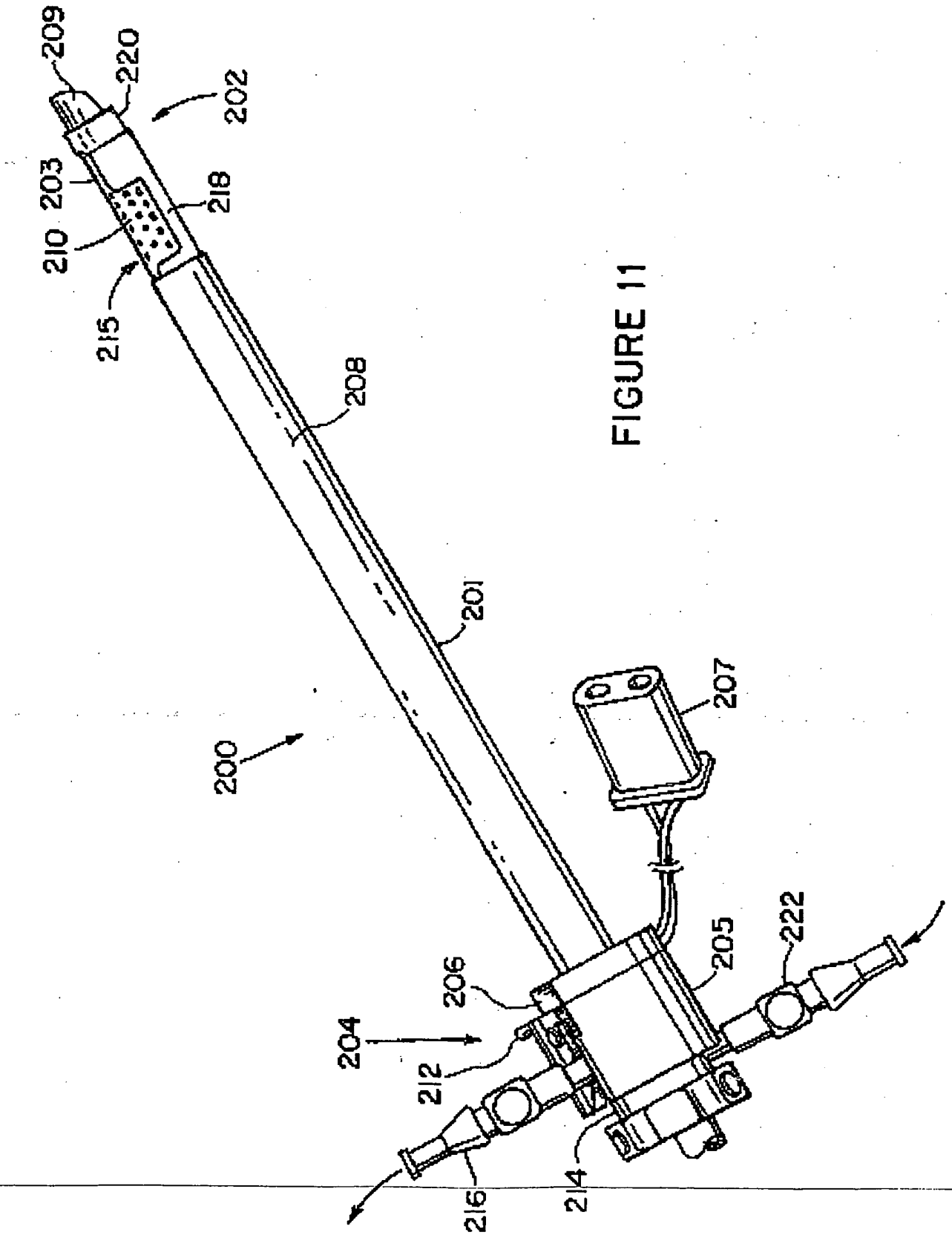
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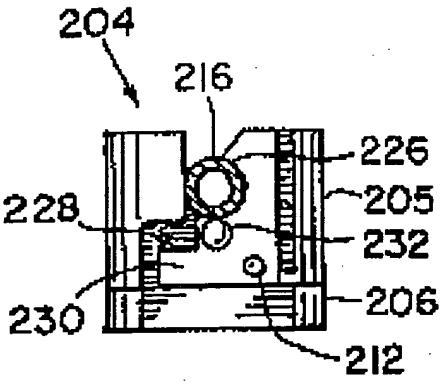
FIGURE 11



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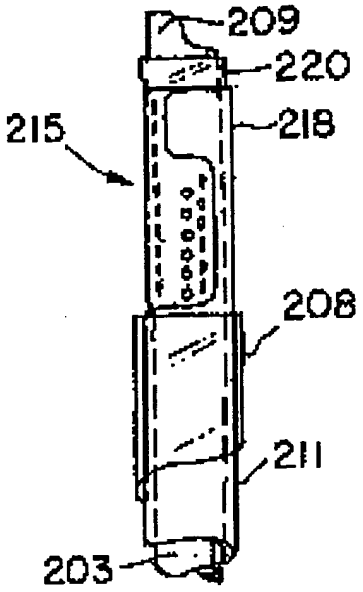

FIGURE 13A

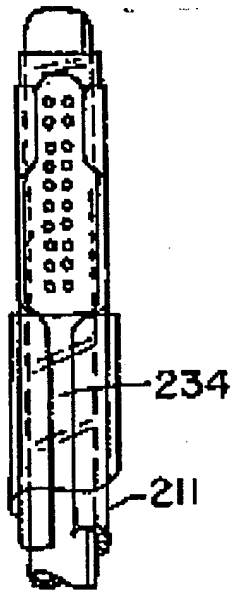

FIGURE 13B

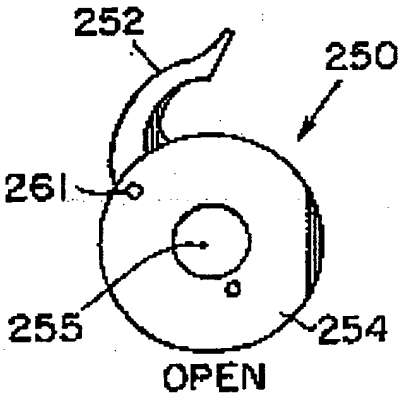

FIGURE 14A

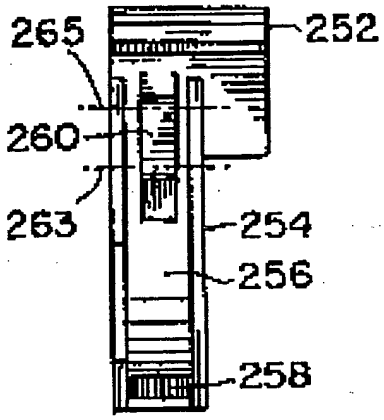

FIGURE 14C

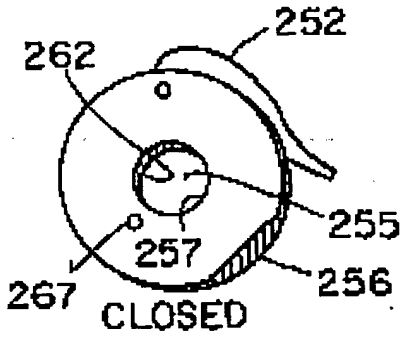

FIGURE 14B

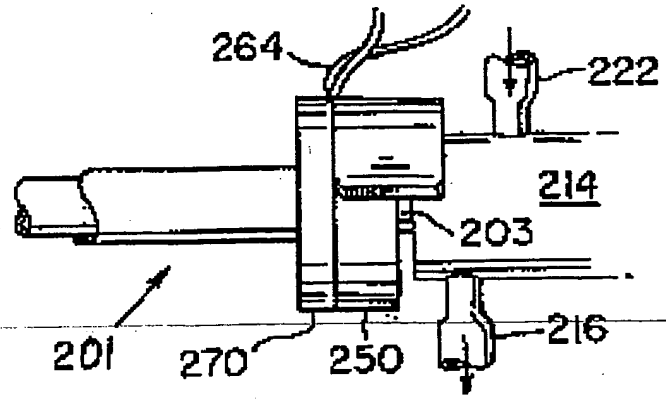

FIGURE 14D

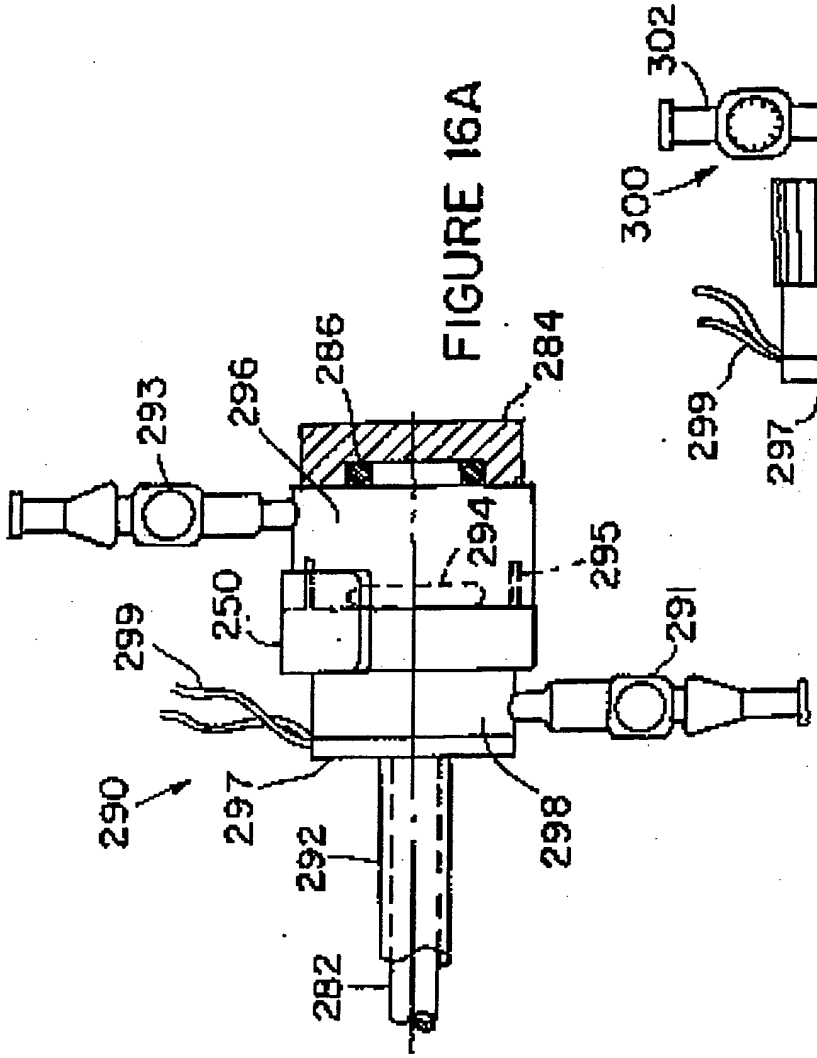

FIGURE 16A

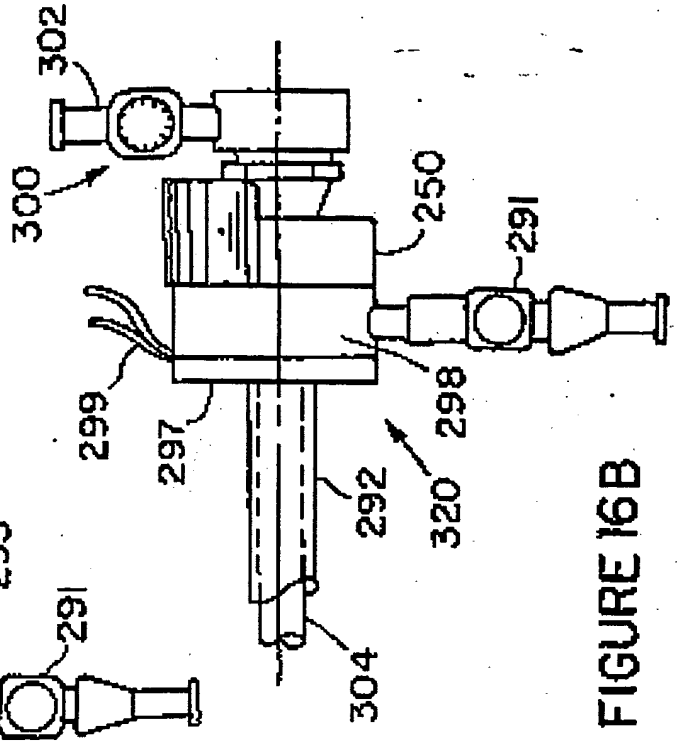

FIGURE 16B

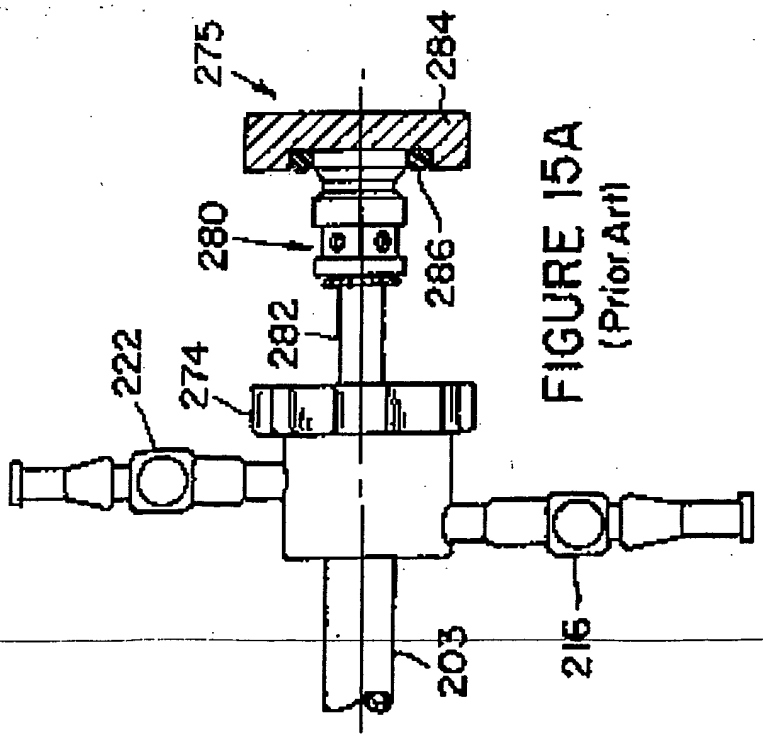

FIGURE 15A
(Prior Art)

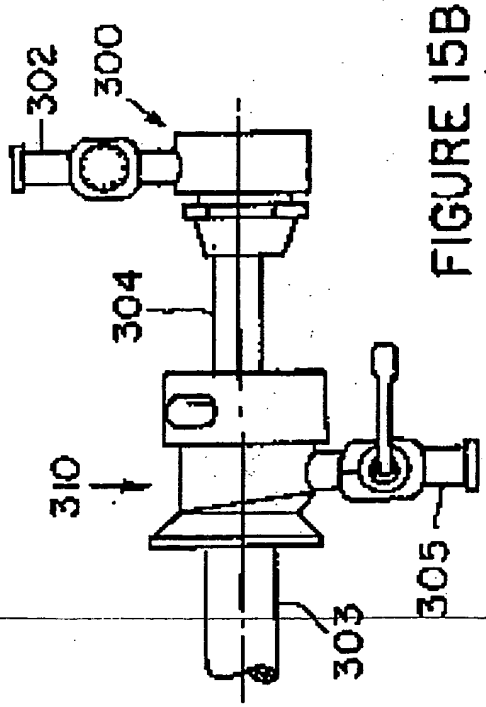

FIGURE 15B
(Prior Art)